EFFICACY OF PIPELLE ASPIRATION IN DIAGNOSING ENDOMETRIAL PATHOLOGY *IN* PERIMENOPAUSAL WOMEN WITH ABNORMAL UTERINE BLEEDING – A COMPARATIVE STUDY

Dissertation Submitted to the

THE TAMILNADU Dr.M.G.R.MEDICAL UNIVERSITY
CHENNAI

In partial fulfillment
Of the requirement for the degree of

M.S OBSTETRICS AND GYNECOLOGY
BRANCH II

MADRAS MEDICAL COLLEGE
CHENNAI TAMILNADU

APRIL 2016

CERTIFICATE

This is to certify that this dissertation entitled **"EFFICACY OF PIPELLE ASPIRATION IN DIAGNOSING ENDOMETRIAL PATHOLOGY IN PERIMENOPAUSAL WOMEN WITH ABNORMAL UTERINE BLEEDING – A COMPARATIVE STUDY"** has been done by Dr. G. S.Vaishnavi, Post Graduate in M.S (Obstetrics and Gynaecology) under my overall supervision and guidance at Govt. Hospital for Women and Child Health, Institute of Obstetrics and Gynaecology, Madras Medical College, Chennai in partial fulfillment of regulations of TamilNadu Dr.M.G.R. Medical University for the award of M.S. Degree in Obstetrics and Gynecology.

Prof. Dr. S. Sumathy, MD; DGO,
Deputy Superintendent,
Institute of Obstetrics and Gynaecology,
Madras Medical College,
Chennai.

Prof. Dr. Baby Vasumathi, MD.,DGO.,
Director,
Institute of Obstetrics and Gynecology,
Madras Medical College,
Chennai

Prof. Dr. R. Vimala, MD.,
Dean,
Madras Medical College,
Chennai

DECLARATION

I, Dr. G.S.Vaishnavi solemnly declare that the dissertation tiltled **"EFFICACY OF PIPELLE ASPIRATION IN DIAGNOSING ENDOMETRIAL PATHOLOGY IN PERIMENOPAUSAL WOMEN WITH ABNORMAL UTERINE BLEEDING – A COMPARATIVE STUDY"** has been prepared by me. I also declare that this bonafide work or a part of this work was not submitted by me or any other person for any award, degree or diploma to any other university board either in India or abroad.

This is submitted to The Tamil Nadu Dr. MGR Medical University, Chennai in partial fulfillment of the rules and regulations for the award of M.S degree Branch II Obstetrics and Gynaecology to be held in April 2016.

PLACE: **Dr. G. S.Vaishnavi**

DATE

ACKNOWLEDGEMENT

I am very thankful to **Prof. Dr. R. Vimala, MD.,** Dean, Madras Medical College for her kind permission to carry out this study at Institute of Obstetrics and Gynaecology, Chennai.

I express my sincere gratitude and thanks to **Prof.Dr.Baby Vasumathi, MD.,DGO.,** Director, Institute of Obstetrics and Gynecology, Chennai for her guidance.

I sincerely extend my thanks to the Deputy Superintendent, **Prof. Dr. Sumathy, MD.,DGO.** for her encouragement and guidance in conducting the study.

I am very grateful to **Assistant Prof.Dr.Geetha, MD.,DGO** and **Dr. Shanthi, MD.,DGO,** Institute of Obstetrics and Gynaecology, Chennai for their valuable guidance and suggestions in the executing this study.

My sincere thanks to all other Assistant Professors and fellow postgraduates for their help during the course of this study.

My special thanks to my husband **Dr. G. C. Premnivas, Ph.D.,** and my parents for helping me and being a huge moral support.

Lastly and most importantly, I am indebted to all my patients who willingly participated in this study.

CONTENTS

Introduction

INTRODUCTION

The most important step in the assessment of abnormal uterine bleeding is endometrial sampling for histopathology. AUB is a major problem accounting for 33% of outpatient gynecological referrals. This proportion rises to 70% in the perimenopausal and postmenopausal age group. Setzler & colleagues demonstarted that 18% of perimenopausal women had menorrhagia and/or metrorrhagia and one fifth of these were due to premalignant/malignant disease. Endometrial hyperplasia occurs in 5-10% of patients with post menopausal bleeding and around 10% of patients with post menopausal bleeding have endometrial cancer. The diagnosis of endometrial cancer must be considered in perimenopausal women when abnormal uterine bleeding is persistent or recurrent or if obesity or chronic anovulation is present. Endometrial sampling becomes mandatory when a woman is found to have high risk factors for endometrial pathology, such as perimenopausal bleeding, postmenopausal bleeding or history of chronic anovulation.

To date, hysteroscopic directed biopsy and D&C is considered as the standard for sampling the endometrium without its place in gynecology being challenged. But in >60% of D&C, less than half of uterine cavity is curetted, with additional risk of complications of general anesthesia, infection and perforation. This led to the advent of simpler methods for endometrial sampling. One such method is the use of Pipelle. It is a disposable

polypropylene sheath with an inner plunger. It has been found to be very comfortable and has given comparable results as that of tissue obtained from D&C, hysterectomy or stiff metal curette. It does not require a general anesthesia. It can be used by anyone trained in the use of an uterine sound and is simpler than the insertion of an IUCD.

Advantages of Pipelle:

1. It enables quick sampling of endometrium (5-15 seconds) & the entire procedure can be completed within 10-15 minutes.
2. It is safe & its acceptability has been reported in various studies. After successful use in tertiary care practice, it has been introduced into primary care.
3. The Pipelle is cost effective when compared with hysteroscopy.

Concerns regarding use of Pipelle:

1. Adequacy of sample obtained
2. Nonsampling of focal intrauterine lesions
3. Accuracy of histopathology report of tissuesampled.

This study is being conducted to establish the validity of Pipelle aspiration technique and adequacy of endometrium sampled by Pipelle for histopathology.

Aims & Objectives of the study

AIMS & OBJECTIVES

- The objective of the study is to determine the reliability & accuracy of Pipelle aspiration in acquiring an adequate and representative endometrial sample and to compare its histopathology with hysteroscopic directed biopsy.

- The primary outcome measurement will be the validity of the Pipelle aspiration technique for determining the histopathology of endometrium in women who present with abnormal uterine bleeding.

- The secondary outcome measurement will be the adequacy of the tissue sample for histopathology and associated complications of procedure.

Review of Literature

REVIEW OF LITERATURE

NORMAL MENSTRUAL BLEEDING

Normal menstrual bleeding is physiological phenomenon with cyclic menstruation occurring every 21–35 days that lasts fewer than 8 days with 20–80 ml of blood loss.The ordered sequence of endocrine signals and ovulation characterize the menstrual cycle leading to regularity, predictability and consistency of menstruation.

DEFINITIONS

1. Polymenorrhea is uterine bleeding at intervals of less than 21 days.
2. Oligomenorrhea is uterine bleeding at intervals of more than 35 days.
3. Menorrhagia (Hypermenorrhea) is excessive uterine bleeding at regular intervals.
4. Hypomenorrhea is scanty uterine bleeding at regular intervals.
5. Metrorrhagia isuterine bleeding at irregular intervals that is normal in amount.
6. Menometrorrhagia is heavy, irregular bleeding.
7. Intermenstrual bleeding is bleeding between regular menses.

The causes of abnormal uterine bleeding may be categorized as either:

I) Organic

II) Nonorganic

ORGANIC CAUSES OF AUB:

It includes reproductive tract diseases, systemic diseases, trauma and may bedue to pharmacologic alterations.

NONORGANIC CAUSES OF AUB:

The diagnosis of nonorganic cause or Dysfunctional Uterine Bleeding (DUB) is assumed when organic causes are excluded.

TYPES OF DUB:

- Anovulatory 80%
- Ovulatory 20%

TABLE 1: CLASSIFICATION OF DUB

ANOVULATORY	OVULATORY
Threshold bleeding of puberty	Irregular ripening
Metropathiahemorrhagica	Irregular shedding
Menorrhagia	
Perimenopausal DUB	

ANOVULATORY DUB:

It is characterized by irregular short cycles with scanty flow or a period of amenorrhea followed by prolonged and irregular bleeding. It occurs usually due to alteration in hypothalamic-pituitary-ovarian axis. It is common in the extremes of reproductive life and also in PCOS. There is unopposed estrogenic stimulation of the endometrium which results in a persistent proliferative or hyperplastic pattern. This estrogen withdrawal bleeding is characteristically painless.

Metropathia haemorrhagica is a type anovulatory DUB characterized by a certain period of amenorrhea followed by prolonged and heavy bleeding. It is due to hyperestrogenism. There is associated cystic glandular hyperplasia of the endometrium. The ovaries may show a multicystic picture due to follicular cysts. There is a future risk of endometrial cancer.

OVULATORY DUB:

Factors responsible for ovulatory DUB is thought to originate in the endometrium itself. It is thought to be due to a shift in endometrial conversion from vasoconstrictor prostaglandin PGF2alpha to the vasodilator prostaglandin PGE2 and prostacyclin. Other contributory factors include reduced endothelins which are potent vasoconstrictors.

IRREGULAR RIPENING is characterized by premenstrual spotting. It is considered to be due to inadequate functioning of the corpus luteum.

IRREGULAR SHEDDING is caused by persistence of corpus luteum that results in postmenstrual spotting or prolonged menses.

PERIMENOPAUSE

Perimenopause or the menopausal transition (MT) is defined by World HealthOrganization as the period beginning 2-8 years prior to the final menstrualperiod. Treolar et al followed 2700 American womenwith menstrualdiaries for 29 years and described changes that occurred with reproductive aging. The midreproductiveage group (20-40 years) were characterized by regular cycles with a gradual decrease in total cycle length of 2-3 days. Irregularity increased after 40 years of age, primarilyoccurring approximately 7 years before menopause.

BLEEDING PROBLEMS IN PERIMENOPAUSE

AUB is a frequent clinical condition accounting for about 70% of all gynecological visits by perimenopausal women. There is no consistent expected uterine bleeding pattern which can be considered normal during perimenopause. As with perimenarchal girls, anovulatory uterine bleeding from dysfunction of hypothalamic–pituitary-ovarian axis is a more common finding in this group. Alternatively the incidence of bleeding due to pregnancy and sexually transmitted disease decreases. With increasing age there is greater risk

of benign & malignant tumours. For example, Setzler and colleagues studied the charts of 500 perimenopausal women and characterized alterations in their menstrual flow. They found that 18% had menorrhagia and/or metrorraghia and one fifth of these were due to premalignant or malignant disease. About 70% of perimenopausal women had reduced frequency whereas only 12% actually stopped bleeding.

THEORIES ON PERIMENOPAUSAL AUB

Several theories have been proposed to elucidate the hormonal mechanisms responsible for perimenopausal bleeding. In one theory, ovulation occurs but with a prolonged follicular phase, during which there is a slow rise in the estrogen level. This slow rise in the stimulus from estrogen causes the endometrium to proliferate excessively. This lengthened follicular/proliferative phase results in a heavier, longer menstruation after progesterone is withdrawn. When abnormal bleeding is primarily anovulatory, FSH stimulation is insufficiency. Abnormal estrogen production can also inhibit the LH surge with resultant anovulation. The primary follicle continues to produce estrogen again. This causes prolonged endometrial stimulation. This continues until either the estrogen level declines resulting in bleeding or until the disorganized endometrium promotes unpredictable, irregular bleeding. This theory is supported by the fact tha tperimenopausal women have been found to develop a relatively hyperestrogenic state with inadequate progesterone support as seen by diminished luteal phase pregnanediol excretion.

Increased estrogen levels causing prolonged endometrial stimulation in longer anovulatory cycles may well contribute to the rising incidence of endometrial hyperplasia, myomas and dysfunctional uterine bleeding as women traverse through “Menopause Transition”.

EVALUTION OF ABNORMAL UTERINE BLEEDING

The evaluation of the patient begins with history taking, general examination and pelvic examination including cervical cytology. Age, weight, previous menstrual patterns, medical problems are most important in diagnosis. Furthermore, questions about of the broad categories of AUB (pregnancy complications, bleeding diathesis, anovulation and structural lesions) helps to avoid omitting important history.

Pregnancy

Knowing the usual menstrual pattern, the date of the last menstrual period and the possibility of exposure to pregnancy should be initial questions.

Coagulation abnormalities

When there is a bleeding diathesis, menorrhagia is the common presentation. Family history of bleeding diatheses, history of frequent epistaxis, frequent bleeding of the mucous membranes , excessive bleeding with previous surgery etc. gives a hint to diagnosis.

Anovulation

Periodical menstruation provide over a 95% probability that a woman is ovulating. Whereas anovulatory bleeding is typically noncyclic with an unpredictable pattern ranging from prolonged bouts of spotting to outright hemorrhage. In comparison to an ectopic pregnancy, anovulatory bleeding is usually painless. The most common causes of anovulation are PCOS, thyroid disorders, hyperprolactinemia, and eating disorders. Hence disease and medication specific questioning of the patient must be carried out when anovulation is suspected.

Structural

Metrorrhagia superimposed upon normal cyclic bleeding is often associated with uterine structural lesions. As the lesions may present with menorrhagia and/or metrorrhagia, the bleeding pattern for women with focal structural lesions such as fibroids and polyps is not specific. Metrorrhagia is more commonly seen with intracavitary lesions, whereas menorrhagia is associated with intramural or partially submucosal lesions. The AUB associated with diffuse uterine lesions (hyperplasia/endometrial carcinoma) also tends to be unpredictable as bleeding from these lesions is generally superimposed upon long-term anovulatory patterns of AUB.

PHYSICAL EXAMINATION

A systematic approach to the physical examination is essential. Physical examination begins with general examination of the patient focusing on signs of anaemia, thyroid disorders, bleeding diatheses etc. Visual inspection of the cervix is essential to confirm a uterine source of bleeding. The uterine size, contour, firmness, mobility, position and tenderness suggests the presence of fibroids, adenomyosis, other pelvic neoplasms, pregnancy, Mullerian anomalies and infections. Likewise, adnexal examination helps distinguishing adnexal masses, ectopic pregnancy, polycystic ovaries and pelvic inflammatory disease (PID).

The mere presence of anatomic lesions does not assure that they are the source of AUB. Therefore, a comprehensive investigation of all possible causes is vital in all cases of AUB. Response to treatment is ultimately required to help confirm a structural source ofAUB.

TABLE 2: INVESTIGATIONS

SYSTEMIC CAUSES	INITIAL INVESTIGATIONS
Thyroid disorders	Sensitive thyroid-stimulating hormone test
Polycystic ovary syndrome	Free testosterone, DHEAS, luteinizinghormone : follicle stimulating hormone>3:1
Coagulopathies,leukemia, thrombocytopenia	Complete blood count, INR, partial thromboplastin time, bleeding time
Hepatic disease	Liver function tests, INR
Renal disease	Creatinine
Pituitary adenoma or hyperprolactinemia	Fasting prolactin
Adrenal hyperplasia Cushing disease	DHEAS, free testosterone 24-hour urine free cortisol, overnight dexamethasone suppression test

DIAGNOSTIC PROCEDURES

The following are the various diagnostic procedures for AUB.

I.Endometrial biopsy

When the source of the bleeding is found to be the uterine cavity, sampling of the endometrium for pathology examination is usually mandatory. D&C was traditionally the method of choice for investigating patients with postmenopausal bleeding. However in about 60% of the D&C procedures less

than half of the uterine cavity is curetted. Most focal lesion (polyps and fibroids) is missed by D&C in postmenopausal women with AUB. Another disadvantage of D&C is that this procedure is performed under general anesthesia in an inpatient setting. D&C is now considered to be an outdated practice and is replaced by less invasive outpatient evaluation techniques using endometrial biopsy devices and outpatient hysteroscopy guided biopsies. Endometrial biopsy has been performed as an outpatient setting since 1935. In 1970's Vabra curette was introduced followed by the Pipelle in the 1980's.

II. Novak curette

Novak curette was the standard instrument in practice for many years. It is made up of Stainless steel and is non-disposable. The cannula of the curette is rigid and is attached to the non cutting end of the curette by a syringe plunger. It is most commonly used as a miniature curette that contains a serrated edge surrounding its biopsy aperture, though it was initially devised to obtain a sample of the endometrium by suction and aspiration. The curette is about 5 mm in diameter and usually passes without dilatation through a small cervical canal, even in nulliparous women. Sometimes the postmenopausal cervical canal is stenotic and difficult to penetrate. The sensitivity, specificity and predictive values for the Novak type of curette in the detection of endometrial cancer has not been determined accurately.

The main disadvantages with metal curettes include patient discomfort, cost and procedural complications such as uterine perforation and infection.

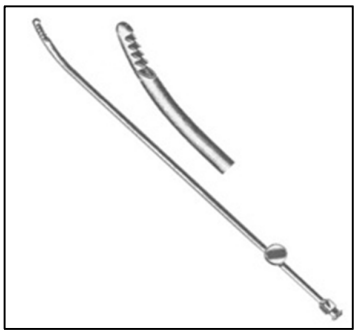
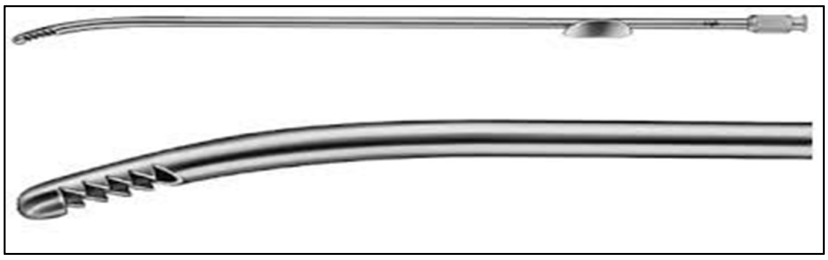


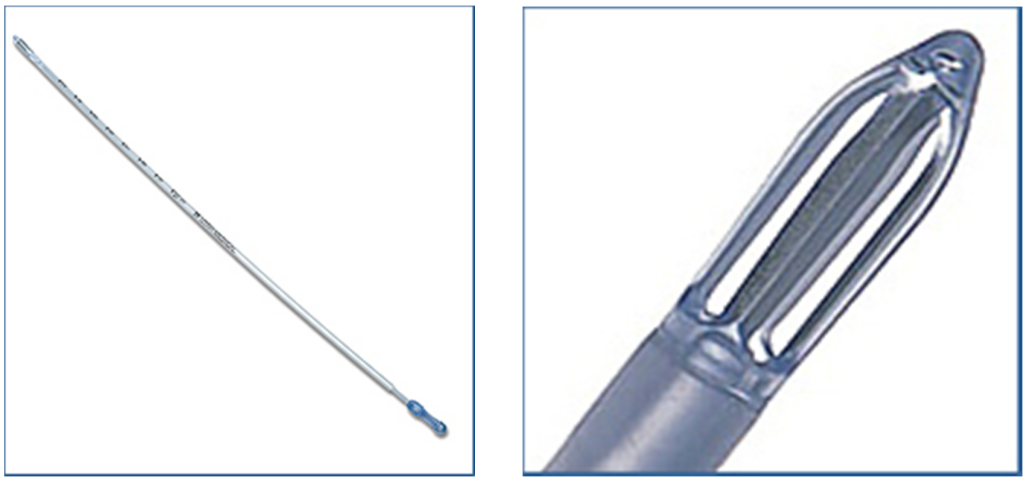
FIGURE 1: NOVAK CURETTE



III. Silastic curettes

These have a smaller diameter (3 mm), are flexible and are better tolerated by patients. There can be difficulty to pass it through a truly stenotic cervix because of their pliability. Often there is an accompanying syringe that attaches to develop an effective vacuum pressure to improve the size of the sample obtained.

FIGURE 2: SIALISTIC CURETTE



IV: Vabra aspirator

It is been used extensively over the past 20 years. This disposable device requires an external vacuum source, usually an electric pump. It can be quite noisy and startling to the patient. The cannula is commonly plastic, with a 4mm diameter, although 2and 3mm stainless steel curettes are also available. A circumferential in-and-out motion is used to obtain a sample. Patient discomfort usually necessitates intravenous analgesia. Moreover, if the cervix is stenotic, cervical dilation may be necessary before sampling as the larger cannulas may be difficult to introduce. However Vabra aspiration produces a sample comparable to that obtained with dilatation and curettage.

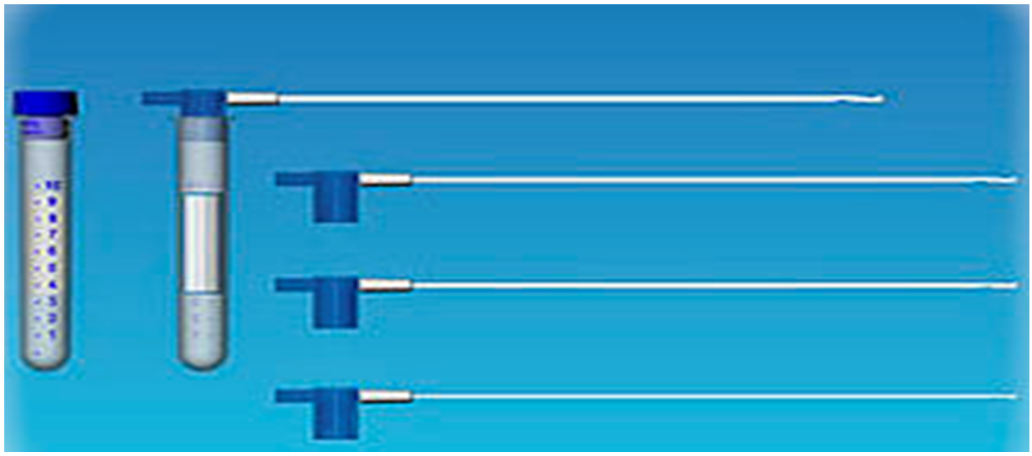


FIGURE 3: VABRA ASPIRATOR

V: Karman cannula and syringe

Unlike the Vabra aspirator, the Karman cannula and syringe does not require an external vacuum source. The cannula is usually 4 to 6 mm in diameter and is made of flexible plastic. It has two ports at the distal end. The cannula is disposable, while the syringe, which produces the vacuum, can be reused. To obtain an adequate sample, circumferential in-and-out motion is required. Intravenous analgesia may be necessary. It has similar diagnostic accuracy as that of dilatation and curettage.

FIGURE 4: KARMAN CANNULA

VI. Pipelle

The Pipelle has become one of the most popular new devices as it requires little expertise and can be used by anyone experienced in using the uterine sound. It was developed by Cornier. It was originally employed for endometrial sampling in fertility studies, but its usefulness in the diagnosis of endometrial pathological lesions was soon realized. Pipelle is a disposable flexible polypropylene sheath 23.5 cm long with a soft rounded end. It has an outer diameter of 3.1 mm and inner diameter of 2.6 mm. It has an inner piston which is drawn back quickly after the device is inserted in the uterus so that a negative pressure is created allowing tissue to be sucked through a perforation of 2.4mm from the endouterine end.

When sampling is complete, the core of tissue is expelled in a bottle containing formalin solution and is sent for histopathological examination.

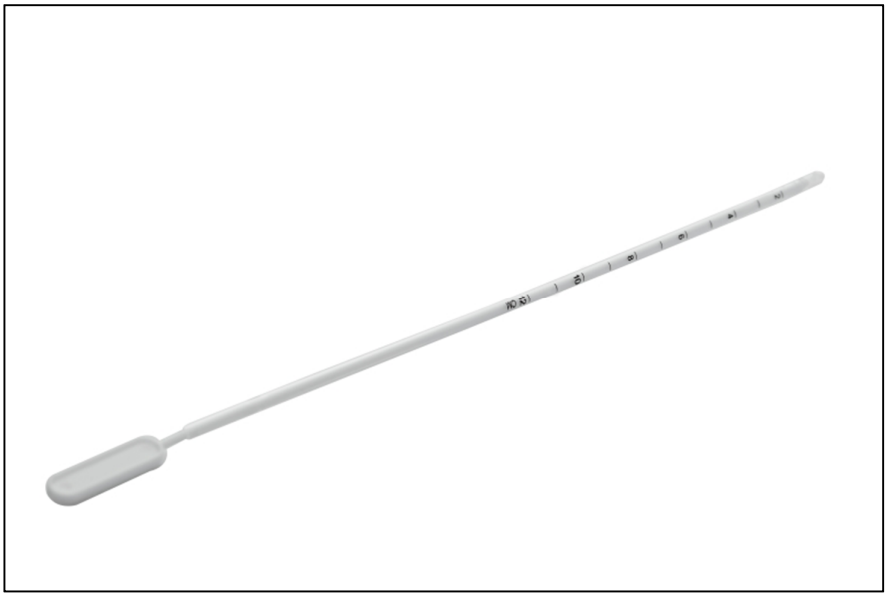


FIGURE 5: PIPELLE

The Pipelle curette offers two advantages:

1. It can traverse most cervical canals without prior dilation or use of a vulsellum.
2. It is generally well tolerated without analgesia.

PIPELLE ENDOMETRIAL SAMPLING - WHAT DO STUDIES SAY

In his first series Cornier found 4 cases of endometrial cancer in 75 women with unexplained vaginal bleeding. Studies in women with known endometrial cancer have shown Pipelle to be sensitive, although small localized lesions may be missed. When compared with conventional D&C, the Pipelle has proved good. It is less painful than the Novak, preserves the architecture of the stroma better and is much cheaper. Some investigators were worried that the Pipelle might sample less of the endometrium, although this was not reflected in lower diagnostic accuracy. Dijkhuizen et al conducted a review of the studies containing information regarding the accuracy of endometrial sampling using 18 different devices from 1966 to 1999. They identified 39 informative studies involving 7914 women. The studies included combinations of menopausal and/or perimenopausal women. Either subsequent formal D&C or hysterectomy was used as a reference compared with office endometrial biopsy. Diagnostic accuracy was found to be better in menopausal women. Yet overall, accuracy was good in all women, especially with the use of the Pipelle where sensitivity for endometrial carcinoma was 99.6% and specificity was

91%. Sensitivity for atypical hyperplasia was 81% with a specificity exceeding 98%.

A similar systematic review was done by Clark et al involving 1013 patients from 11 primary studies using 6 different commercial clinic biopsy instruments. They identified good accuracy for a biopsy to identify endometrial cancer provided the specimen was adequate for evaluation. The failure rate for obtaining an adequate specimen was 7%.

Biopsy failure was more common in menopausal women. When a biopsy was found to be positive for cancer, the post biopsy probability of endometrial cancer was 81.7% (95% confidence interval (CI) 59.7-92.9). The probability that a negative biopsy missed an endometrial cancer was 0.95 (95% CI;0.4-2.4).

Endometrial sampling is associated with a greater percentage of false-negative results in case the pathology is local, such as endometrial polyps. Guido and associates (1995) reported false negative results in 11 out of 65 patients-17%-undergoing pipelle endometrial sampling for abnormal bleeding. Five of these 11 had malignant tissue present only in endometrial polyps and another 3 patients had disease localized to less than 5% of the endometrial surface. Hence a positive result was accurate in the diagnosis of endometrial cancer whereas a negative result was not. Therefore, if an endometrial biopsy is negative in a situation where AUB continues or if a biopsy cannot be obtained, then further more aggressive diagnostic efforts is recommended .

Adequacy of sample

Several studies comparing the ability of pipelle to obtain adequate sample, with that of D&C have shown a comparable results to detect abnormalities. In a meta-analysis comparing endometrial sampling techniques, the pipelle was found to be most accurate. Among postmenopausal women, it showed a sensitivity of 81% for detection of atypical endometrial hyperplasia and 99.6% for detection of endometrial cancer. The sensitivity of the device for the detection of endometrial cancer among perimenopausal women was 99.6% and the specificity of the pipelle device for diagnosing endometrial hyperplasia or malignancy was 98%.

In a study by ShaziaFakhar et al (2008) pipelle had a sensitivity, specificity, positive predictive value and negative predictive value of 100% for diagnosing endometrial carcinoma, hyperplasia and secretory endometrium. Pipelle also had high diagnostic sensitivity, specificity, and negative predictive value (100%, 98% and 100% respectively) for hyperplasia with atypia, and low sensitivity (57%) and positive predictive value (57%), but high specificity (97%) and negative predictive value for endometritis. Similarly, for proliferative endometrium, the pipelle technique had values of 94% and 93% for sensitivity and specificity respectively. Both samples labeled as inadequate for histology by pipelle were polyps on the D&C report.

In another comparative study by Naderi.T & co (2006) comparing the diagnostic accuracy of pipelle biopsy, D&C and hysterectomy, pipelle and

D&C in 89% of cases, pipelle and hysterectomy in 80% of the cases and D&C and hysterectomy in 90% of cases proved agreement, that shows no significant difference in diagnostic accuracy among three methods. Considering high accuracy between the pathological reports of Pipelle which is an outpatient method and those of D&C and hysterectomy, Pipelle sampling is suggested as the first-line diagnostic procedure, while D&C and hysterectomy that necessitate anaesthesia, are time consuming and expensive should be reserved for special cases.

AjitKuruvilla et al (2004) reported histological diagnoses were obtained in 68.6% of patients with pipelle in a sample size of 102 cases. Out of the 32 cases with inadequate or no sample, 22 were endometrial polyps. One report of an inadequate sample was diagnosed to be endometrial hyperplasia on further investigation.

Cost effectiveness

Feldman et al tried to identify an optimal evaluation strategy for patients of various ages and risks for endometrial cancer and for complex hyperplasia who present with a first episode of postmenopausal bleeding. Office biopsy was found to be the most cost effective initial strategy.

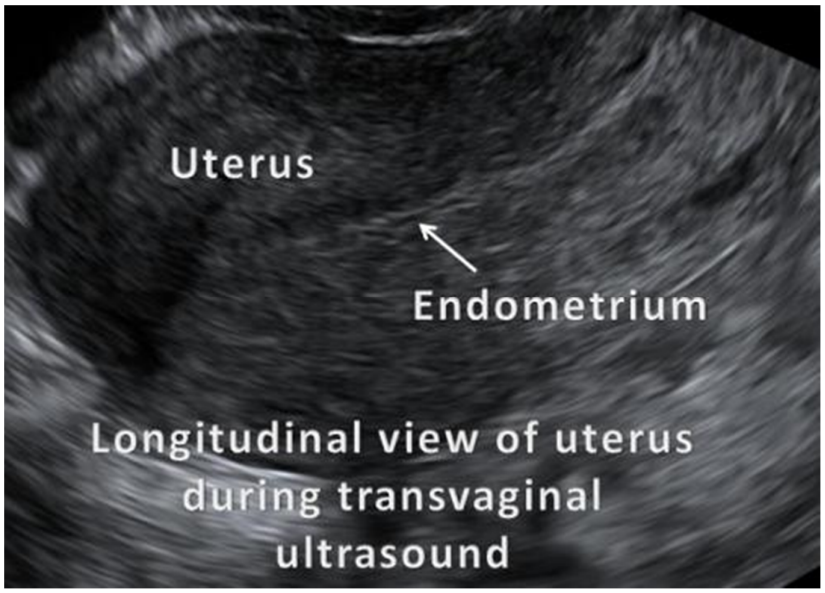
Pain related to the procedure

Silver et al conducted a randomized study comparing Novak and Pipelle endometrial biopsy instruments with respect to quality of the biopsy obtained and pain related to the procedure. Both the instruments yielded biopsies of similar quality (p = .856). Pain scores were lower for the Pipelle (p=.001).

VII: Transvaginal ultrasound

Uterine ultrasound has become another tool in the assessment of the endometrium. An increase in endometrial thickness may indicate a pathological process. Abdominal, or increasingly transvaginal, ultrasound may be used alone or in combination for the investigation of abnormal bleeding. But several studies suggest that the combination of Pipelle sampling and ultrasound can achieve 100% diagnostic accuracy.

FIGURE 6: TRANSVAGINAL USG NORMAL APPEARANCE



During menstruation, the endometrium appears as a thin, echogenic line of about 1–4 mm in thickness. The endometrium is usually best seen on transvaginal scans. Endometrial thickness is measured from echogenic border to echogenic border across the endometrial cavity on a sagittal midline image. Once the proliferative phase of the menstrual cycle (days 6–14) begins, the endometrium becomes thicker (5–7 mm) and more echogenic, relative to the myometrium. It reflects the development of glands, blood vessels, and stroma. In the late proliferative (periovulatory) phase, the endometrium develops a multilayered appearance with anechogenic basal layer and hypoechoic inner functional layer, separated by a thin echogenic median layer arising from the central interface or luminal content. Now the endometrium usually measure up to 11 mm thickness. The layered appearance usually disappears 48 hours after ovulation. During the secretory phase, the endometrium becomes even thicker (7–16 mm) and more echogenic. This increased echogenicity is related to stromal edema and glands distended with mucus and glycogen. The endometrium typically reaches a maximum thickness during the mid-secretory phase. There is cyclic ovarian changes that parallel the endometrial changes in the follicular and luteal phases.

VIII: Sonohysterography

Sonohysterography (SHG) is also known as hysterosonography, saline infusion sonography, hydrosonography and saline contrast hysterosonography. It is more expensive and invasive compared to TVS and transabdominal ultrasonography.It requires infusion of sterile saline into the uterine cavity during transvaginal sonography. Another disadvantage is that optimally it should be done in the proliferative phase after the menses so that menstrual tissue does not give false positive results and so that thick secretory endometrium is less likely to conceal focal lesions. Its advantage lies in separating and clarifying the relationships of anatomic lesions in and round the endometrial myometrial junction. The size and depth of fibroids into the myometrium can be ascertained to assist in surgical removal. It may also allow the ability to visualize the mobility of intracavitary lesions such as adhesions and polyps within the liquid media. This is not possible with simple sonography due to compression of the structures within the cavity.

FIGURE 7: SALINE INFUSION SONOGRAPHY

IX: Hysterosalpingography

HSG can reliably identify uterine anomalies and intracavitary masses like submucous fibroids and polyps. Disadvantages include its inability to consistently identify diffuse lesions, the sites of attachment of intracavitary masses, intramural or subserosal lesions and the relative invasiveness (pain and radiation exposure) of the procedure. In addition, there is a risk that intracavitary blood clots associated with AUB will yield false positive findings. Therefore hysterosalpingography is not used primarily in the diagnosis of AUB.

X: Hysteroscopy

History and development:

The hysteroscope that is being used today has evolved over the past 175 years. The first hysteroscopy was described by Pantaleoni in 1869.Alfred Heineberg presented a new hysteroscope in 1914. Dr. Herold Seymour used a hysteroscope with a light at the proximal end in 1925. Carl Schroeder offered the first pictures taken through Hysteroscope in 1934. Marleschki presented the contact hysteroscope in 1965. The Hamou Microhysteroscope that was developed in 1980 consisted of a 25 cm long 4mm diameter sheath endoscope with a 90-field angle and was called a microcolpohysteroscope.

THE HYSTEROSCOPE

There are a range of hysteroscopes starting from the 1.2mm flexible hysteroscope with a 2.5mm diagnostic sheath to the standard 4mm scope with a 5mm diagnostic sheath.

a. THE BETTOCHI HYSTEROSCOPE

It can be used as a panoramic hysteroscope as well as a microcontact hysteroscope.

For diagnostic purpose, it can be used with a single flow outer sheath of 3.6mm or a continuous flow outer sheath of 4.4mm. For operative hysteroscopy, it can be combined with a continuous flow operative sheath of 3.9mm*5.9mm to accommodate 5 French instruments.

b. THE VERSASCOPE SYSTEM

It is a flexible telescope that is used with a continuous flow diagnostic cum operative sheath, which has an outer diameter of 3.5mm and a distal curvature of 10 degrees. A proximal collar is rotatable for full peripheral viewing. The operative channel has an expandable instrument channel which easily accommodates instruments till 7 French in diameter.

LIGHT SOURCE

a. HALOGEN

This 150-250 watt cold light sources tends to give a reddish tinge to the image.

b. XENON

A 175 watt xenon light gives an outstanding illumination and enables a good depth of field.

ENDOSCOPIC CAMERA AND MONITOR

It is preferable to use cameras with zoom system to select appropriate size of the image. A single chip endoscopic camera is sufficient for diagnostic and minor operative work.

DISTENSION SYSTEMS

a. CARBONDIOXIDE

It gives excellent visualisation. With carbondioxide, the pressure must be kept in the 100 to 120 mm Hg range with a flow rate of 30 – 60ml/minute, corresponding to intrauterine pressure of 40 to 80 mm of Hg.

Advantages:

Provides clean medium, permits excellent visualization, provides adequate distension of the uterine cavity.

Disadvantages:

Obscured vision even with a mild contamination of the lens with blood or mucus, requires the use of a dedicated gas hysteroflator, high incidence of shoulder and thoracic discomfort and rarely embolism and death.

b. FLUID DISTENSION MEDIA

A. LOW VISCOSITY IONIC MEDIA

It includes normal saline, 5% dextrose, ringer lactate

Advantages:

Prevents hyponatremia, inexpensive, readily available, solution for use with bipolar electrosurgery.

Disadvantages:

Volume overload can cause left heart failure and pulmonary edema, contraindicated for monopolar electrosurgery.

B. LOW VISCOSITY NON-IONIC DISTENSION MEDIA

It includes 3% sorbitol, 1.5% glycine, 5% mannitol

Advantages:

Inexpensive, readily available, media of choice for monopolar electrosurgery.

Disadvantages:

Sorbitol and glycine are hypo-osmolol and can cause hyponatremia; these are associated with cerebral edema, cardiac and skeletal muscle dysfunction

C. HIGH VISCOSITY MEDIA

It includes dextran with 70,000 molecular weight in a 10% water solution (HYSKON)

Advantages:

Small quantities are required for examination, provides excellent visalisation due to its high refractory index and as it does not mix with blood.

Disadvantages:

Expensive, tends to caramelize on instruments, morbidities caused include pulmonary edema, coagulopathies, electrolytes imbalance, anaphylactic reactions.

DISTENSION MACHINES

Endomat is the ideal system as it correctly maintains intrauterine pressure to around 70 mm Hg. Thus it prevents peritoneal reflux and resultant discomfort. But it is very costly.

Indications for Hysteroscopy

a) Unexplained abnormal uterine bleeding
b) Evaluation of endometrial cavity after abnormal hysterosalphingogram.
c) Evaluationof intrauterine adhesions
d) Evaluation of developmental anomalies
e) Unexplained infertility.
f) Recurrent pregnancy loss.
g) Location of displaced intrauterine devices and foreign bodies.

Contraindication for Hysteroscopy

a) Pregnancy
b) Menstruation – a relative contraindication
c) Active or recent endometrial infection
d) Patients with cardiac & pulmonary disease-a relative contraindication.

HYSTEROSCOPY – WHAT DO STUDIES SAY.

Sonja Pop in 2011 studied 239 women with AUB in a period of 12 months. Hysteroscopy with endometrial biopsy was performed in these patients and hysteroscopic and histological findings were compared. The success rate was close to 98% while complications occurred in 0.85% of the cases. The hysteroscopic results were normal in 41% of the patients. Endometrial polyp was the most common finding in postmenopausal women and submucous myoma in perimenopausal women. The sensitivity of hysteroscopy for

detection of intrauterine lesion was 100%, specificity 91%, positive predictive value 93% and negative predictive value 100%.

In a study published by Phalak Rajesh in International Journal of Interdisciplinary and Multidisciplinary Studies involving 50 patients with AUB studied for a period of one year showed the sensitivity of hysteroscopy when compared to histopathological diagnosis was 95%, specificity was 88%, positive predictive value 88%, negative predictive value 96% and diagnostic accuracy was 91.8%.

Elbareg et al evaluated the diagnostic accuracy of hysteroscopy compared to histopathological findings in 280 cases with intrauterine pathology for a period of two years. For benign endometrial lesions, the sensitivity of hysteroscopy was 98.9%, specificity was 97.5%, positive predictive value was 98.8%, negative predictive value was 98.5% with diagnostic accuracy of 98.3%: same parameters for endometrial characterisaton were 78.9%, 90.7%, 82.8%, 90.9% with diagnostic accuracy of 87.8%.

Ariel Revel and Asher Shushan showed that hysteroscopy had a sensitivity, specificity, positive predictive value and negative predictive value of 94.2, 88.8, 96.3 and 83.1% respectively, in predicting endometrial histopathology in 50 infertile women. The highest accuracy of hysteroscopy was in diagnosing endometrial polyp and the worst was in diagnosing endometrial hyperplasia. Since the incidence of focal lesions is high in patients

with AUB, the most beneficial approach is to proceed with hysteroscopy complemented endometrial biopsy.

In an article published by International Journal of Advanced Research in Biological Sciences, 100 egyptian patients above 40 years with AUB were selected including patients who underwent D&C, pipelle and hysteroscopic directed biopsy and hysterectomy within 2 months. The accuracy for D&C, pipelle and hysteroscopy for diagnosing endometrial carcinoma was 81.5, 71.2 and 83.4% respectively, for diagnosing endometrial hyperplasia with atypia were 78.3, 69.2 and 81.2% respectively and for diagnosing endometrial polyp were 25.7, 16 and 91.6% respectively.

HISTOPATHOLOGICAL DIAGNOSIS IN AUB

The 3 sections of a histopathological report are a gross description, the comment section and the final diagnosis. Important information like the tumor size, leiomyoma size, depth of invasion, extent of spread etc. is available the gross examination. The comment section gives a detailed and in-depth description of the pathology. The final diagnosis must be concise with all pertinent information needed to guide therapy. For most pathology/laboratory diagnoses, specificity is greater than sensitivity. A negative diagnosis does not guarantee the absence of disease. In other words, "absence of proof" does not equate to "proof of absence". It is essential to realize that a biopsy or curettage specimen may not have sampled the disease process. As the gynaecologist is

the one with the bleeding patient, further workup is always essential when the pathology report does not confirm the gynecologist's impression.

The etiology for the abnormally bleeding patient is highly dependent upon age. The most common diagnosis is often " no pathology" (usually seen as proliferative or breakdown endometrium), particularly in perimenopausal patients.

I. ANOVULATORY BLEEDING PATTERN (proliferative with glandular and stromal breakdown):

Most cases of DUB are due to anovulatory cycles, especially in perimenarchal and perimenopausal women. Anovulatory cycles are also a component of Stein-Leventhal syndrome or polycystic ovarian disease with more persistent endocrine imbalance in the reproductive years.

In the normal menstrual cycle a cohort of follicles is recruited which begin to develop and produce estradiol. A dominant follicle ruptures following the LH surge at mid-cycle. After the follicle ruptures, a corpus luteum is develops, which produces progesterone as well as estradiol. In anovulatory cycles the follicles are recruited but due to disorders at the hypothalamus/pituitary level or feedback signals, there is no ovulation. As a consequence, there is a estradiol surge without progesterone from a corpus luteum. The follicles either involute leading to estrogen withdrawal or persist causing sustained estrogen stimulation of the endometrium. In either event the

endometrium proliferates without a normal luteal phase. With estrogen withdrawal, there is breakdown in a weakly proliferative background as the estrogen stimulus wanes **(estrogen withdrawal bleeding**). When estrogen persists, the endometrium continues to proliferate with thrombi formation in superficial vessels leading to areas of breakdown (**estrogen breakthrough bleeding**). The breakdown often affects only a portion of the endometrium in either case.

The usual morphological appearance of anovulatory cycles is a proliferative pattern, often with fibrin thrombi in small vessels with breakdown and bleeding superimposed. If there is no active bleeding at the time of biopsy, then the changes are simply those of proliferative phase patterns.

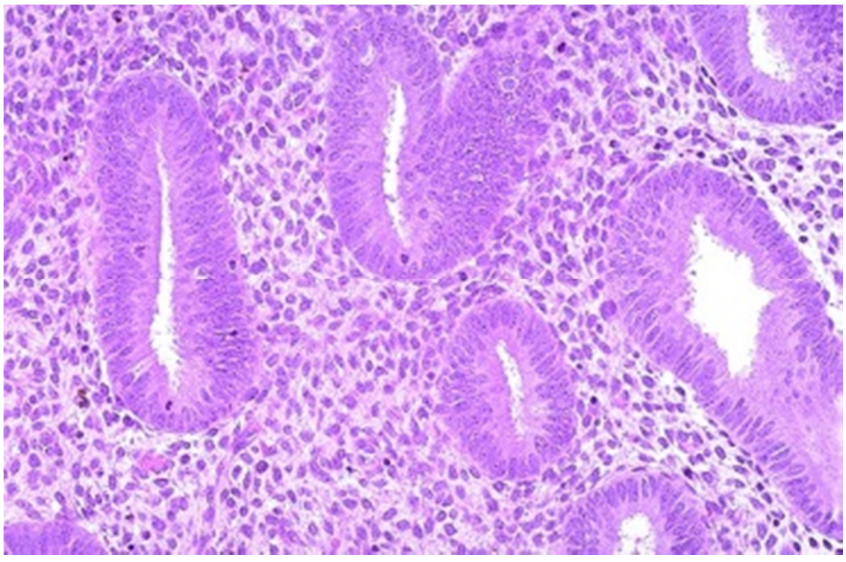


FIGURE 8 : ENDOMETRIUM IN PROLIFERATIVE PHASE

II. SECRETORY ENDOMETRIUM:

DUB may also develop when ovulation is normal but the corpus luteum fails to develop and persist for a normal duration over the second half of the menstrual cycle. Disturbances in the rate and amount of progesterone production by the granulosa cells of the corpus luteum results in alteration in the secretory phase development. These changes may be due to insufficient development or persistence of corpus luteum (**luteal phase defect, LPD**) or due to abnormal persistence of the corpus luteum(**irregular shedding**). These conditions are sporadic and are not amenable to detailed clinical-pathologic correlations to clearly define the morphological changes. There are situations, however, where there is abnormal secretary phase maturation with or without superimposed non-menstrual breakdown. The term **"irregular maturation"** describes the endometrium that show marked variation in secretory development from area to area with some glands demonstrating tortuosity and secretions while other glands being underdeveloped without these changes. It is not clear whether these patterns truly reflect an inadequate corpus luteum.

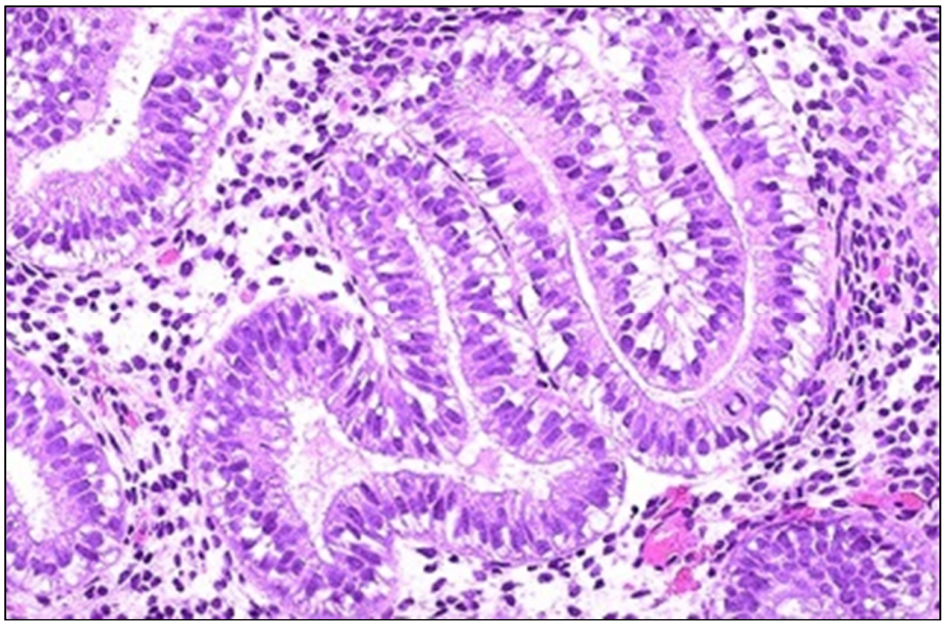


FIGURE 9 : ENDOMETRIUM IN SECRETARY PHASE

POSSIBLE CAUSES OF ABNORMAL SECRETORY PHASE PATTERNS

1. Luteal phase defects
2. Persistent corpus luteum (irregular shedding)
3. Organic lesions (polyps, secretory hyperplasia, etc.)
4. Submucosal leiomyomas
5. Intrauterine adhesions
6. Inflammation
7. Complications of pregnancy
8. Progestin effects

III. ENDOMETRIAL POLYP

An endometrial polyp is a frequent condition and probably is more common than diagnosed. It is easier for the pathologist to diagnose the polyp grossly in the intact uterine cavity after a hysterectomy. During a curetting or biopsy, the biopsy may become piece-meal and this destroys one of the most important clues - that of the polypoid appearance seen histologically as a 3-sided epithelium. Other clues for the diagnosis of the polyp to the pathologist include a fibrous stroma and thick walled vessels.

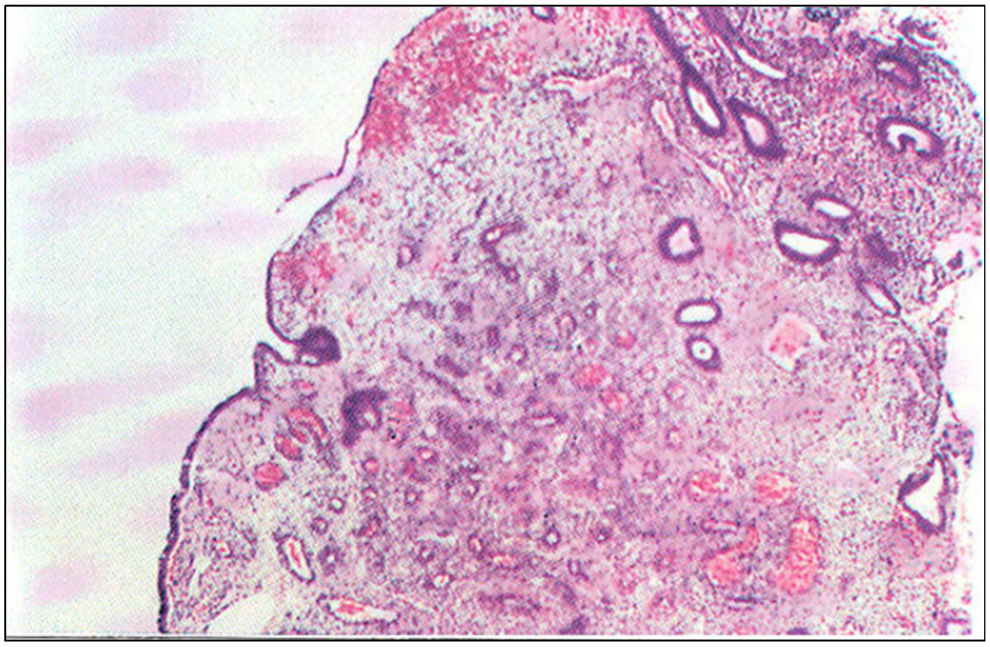


FIGURE 10: ENDOMETRIAL POLYP

IV. DISORDERED PROLIFERATIVE ENDOMETRIUM:

It is an intermediate diagnosis between proliferative type of endometrium and hyperplasia. It is useful to picture endometrial proliferation, usually due to unopposed estrogen, along a continuum of precursor lesions from proliferative - disordered proliferative - simple hyperplasia - complex hyperplasia- adenocarcinoma. There is considerable overlap between these entities.

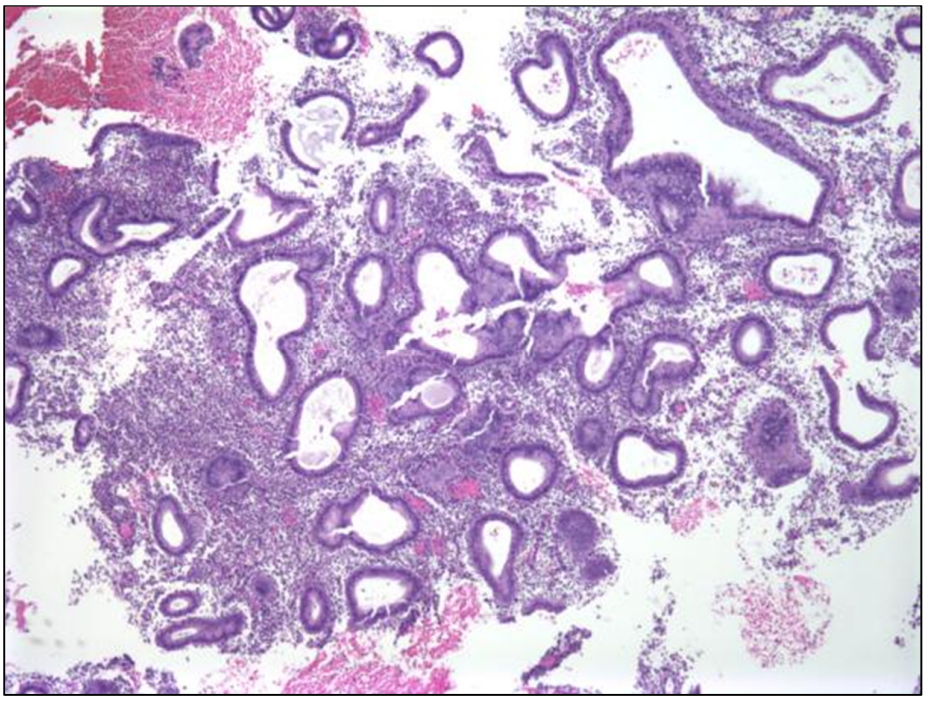


FIGURE 11: DISORDERED PROLIFERATIVE ENDOTHELIUM

V. DISORDERED PROLIFERATIVE PHASE:

The disordered proliferative phase pattern is usually an extension of anovulatory cycles which occurs due to persistent estrogen stimulation. Here the endometrium is proliferative but shows focal gland irregularities including dilatation and branching as that seen in hyperplasia. But in contrast to hyperplasia, however, gland irregularities are only mild and focal in the disordered proliferative phase pattern.

VI. ENDOMETRIAL HYPERPLASIA

The correct definition of endometrial hyperplasia is an increase in glands per unit of stroma. Currently, most pathologists categorise endometrial hyperplasia into simple, complex and atypical hyperplasia.

A. SIMPLE HYPERPLASIA ("hyperplasia with mild architectural and no or mild cytologicatypicality") indicates crowded and often cystically dilated glands with some outpouching and budding (architectural atypia), lined by pseudostratified nuclei that show minimal atypia.

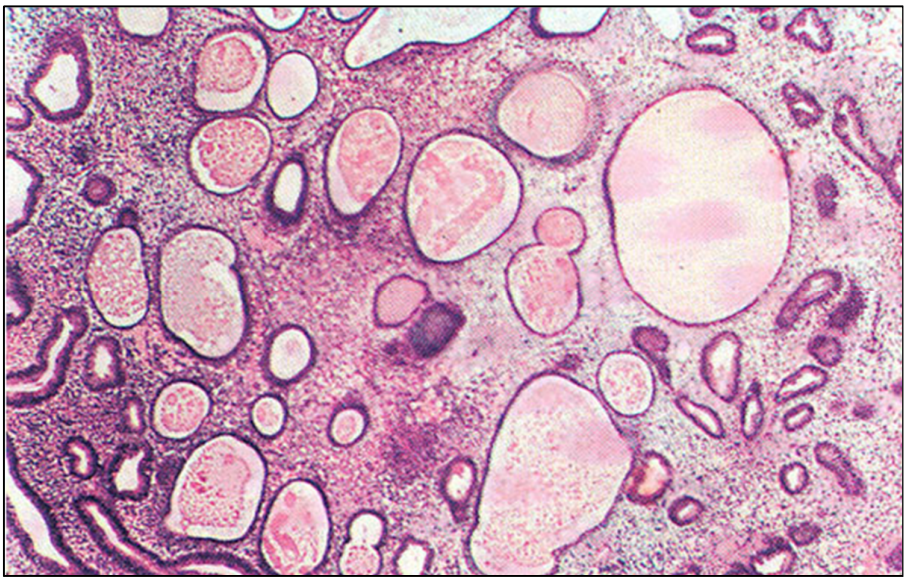


FIGURE 12: SIMPLE HYPERPLASIA

B. COMPLEX HYPERPLASIA ("adenomatous hyperplasia") includes more definite architectural atypicality. Endometrial glands tuft and bud within the lumina giving an irregular pattern and increasing architectural complexity at lower power. Due to these features, the endometrium appears more crowded.

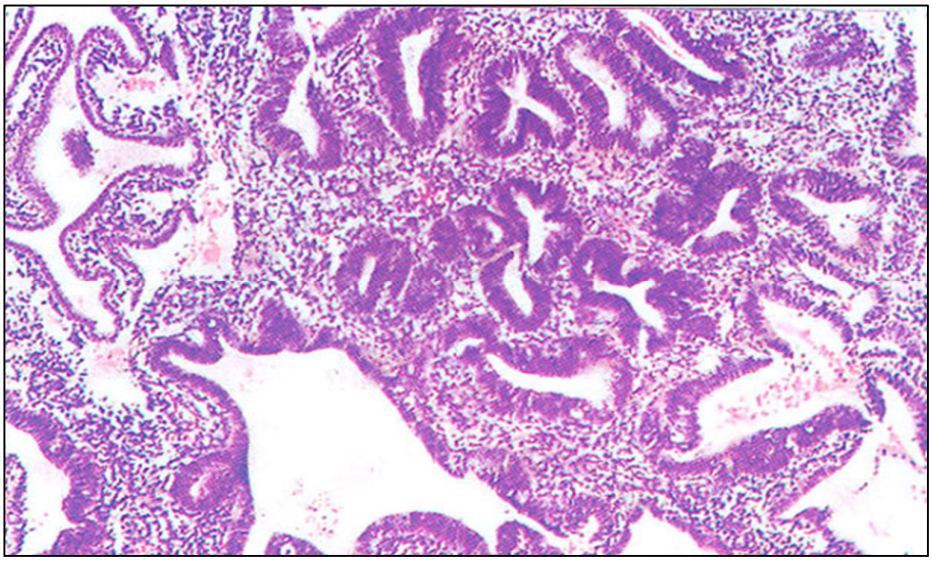


FIGURE 13: COMPLEX HYPERPLASIA

C. ATYPICAL HYPERPLASIA ("complex atypical hyperplasia", "atypical adenomatous hyperplasia") is the most worrisome of the entities and the least likely to be reversible.

The diagnosis of atypical hyperplasia is based uponatypia of the nucleus

FEATURES OF ENDOMETRIAL ATYPIA

1. Enlarged and irregular nuclei
2. Loss of Nuclear polarity
3. Chromatin clumping (vesicular appearance)
4. Prominent nucleoli
5. Cytoplasmic eosinophilia, diffuse or focal.

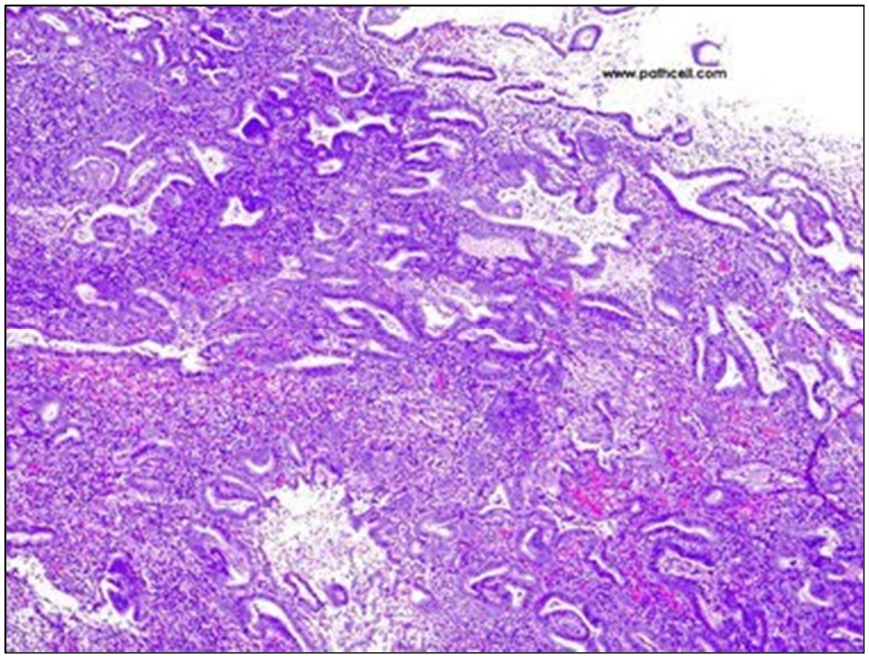


FIGURE 14: COMPLEX HYPERPLASIA WITH ATYPIA

VII. ENDOMETRIAL CARCINOMA:

About 80% of endometrial carcinoma is endometrioid variety. The differentiation of the carcinoma, expressed as its grade by FIGO , is determined by architectural growth pattern and nuclear features. Grade I is 5% or less of the tumour showing a solid growth pattern. Grade II indicated 6 – 50% and grade III more than 50% of the tumour showing solid growth pattern. A well differentiated endometrioid adenocarcinoma demonstrates small, back-to-back glands without intervening stroma, alongwith luminal infolding, budding, papillae and cribriforming.

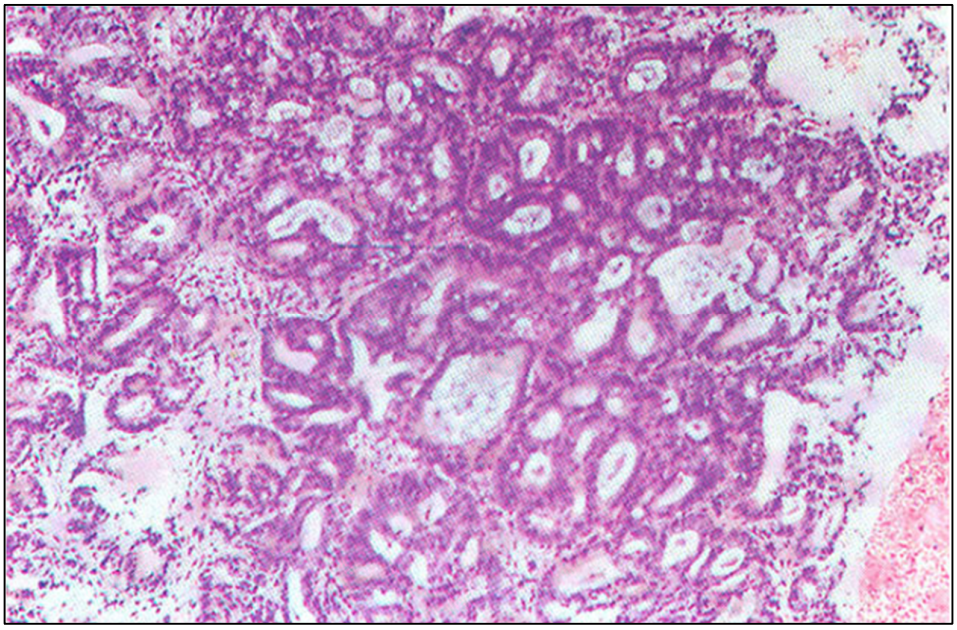


FIGURE 15: ENDOMETRIAL ADENOCARCINOMA

Methodology

METHODOLOGY

Study design:

A prospective observational comparative study evaluating the role of pipelle aspiration as an outpatient procedure in endometrial sampling of perimenopausal women with AUB. 130 perimenopausal women with clinical diagnosis of abnormal uterine bleeding will be selected from the gynaecology OPD of IOG based on the following inclusion and exclusion criteria and will be subjected to endometrial sampling by pipelle followed by hysteroscopy directed biopsy. The efficacy of pipelle will be determined by correlating the histopathological results obtained from it and the hysteroscopy directed biopsy.

INCLUSION CRITERIA

1. Women with age 40 and above with symptoms suggestive of AUB.
2. Patients who do not require emergency management.
3. Not on oral contraceptive pills.
4. No evidence of blood dyscrasias.
5. Women with normal thyroid profile.

EXCLUSION CRITERIA

1. Nulliparous women.
2. Women with postmenopausal bleeding.
3. Patient on contraceptives.
4. Patient with severe anaemia.

PROCEDURE

A complete history was taken and recorded from all the patients thus selected. These patients are subjected to a general and bimanual pelvic examination. Baseline investigations was performed. Anaesthetic assessment was obtained. Endometrial sampling by Pipelle device without anesthesia followed by endometrial sampling by hysteroscope under anesthesia was then done. Both procedures were performed at the same time for the purpose of maintaining synchronicity in the timing of sample.

The patient was made to lie on her back on an examination table with her feet raised and supported by foot rests. Bimanual examination was done to assess the size and position of the uterus. The cervix was then visualized using a vaginal speculum and cleaned. A vulsellum was then applied to the anterior lip of the cervix to provide gentle traction whilst a sound was inserted through

the cervical os. After assessing the position and size of the uterine cavity, the Pipelle was inserted through the cervical os and advanced until gentle resistance was felt.

The inner piston of the device is then withdrawn to create suction and the endometrial sample is obtained by moving the Pipelle up and down within the uterine cavity by approximately 2-3 centimeters, but not beyond the cervical os. The cannula was then rotated during removal and a strip of endometrium is peeled off and sucked into the syringe. This procedure was repeated at least four times and the device rotated 360 degrees to ensure adequate coverage of the area. The Pipelle was then withdrawn from the cervical os and the endometrial sample expelled into a solution of formalin. Following Pipelle procedure, anesthesia was given and hysteroscopy was performed.

Cervix was serially dilated. Hysteroscope was introduced into the uterine cavity. Uterus was visualized completely. Biopsy was taken from all the walls of the uterus. Both samples were sent to a histopathologist who was blinded as to the method of sample collection for histopathology assessment. Endometrial sampling procedure was categorised by the doctor doing it as easy or not easy depending on the difficulty in traversing the cervix, the time taken

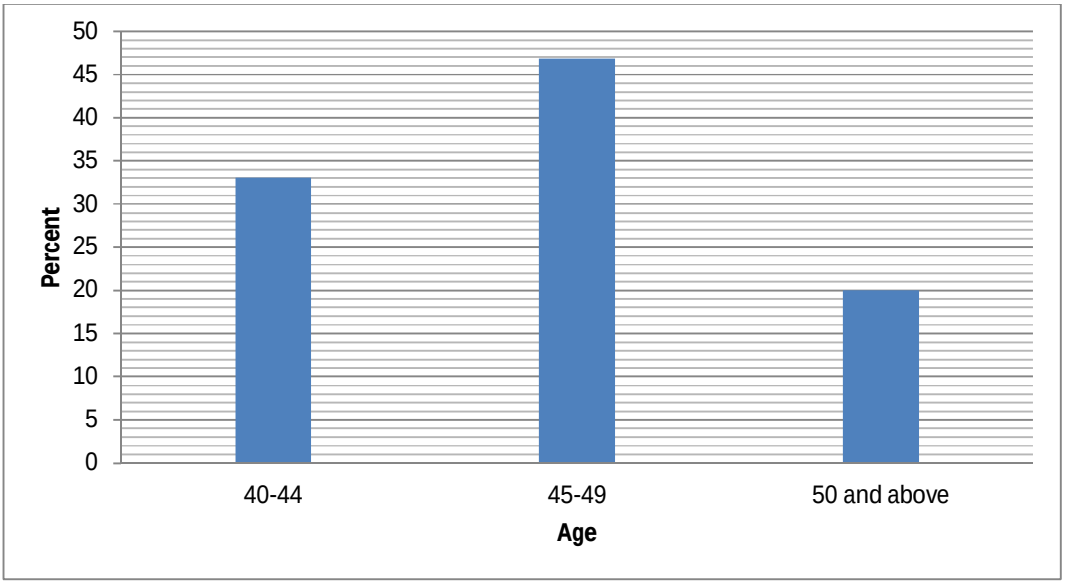
for the procedure. The histopathology report is noted, whether the sample contained endometrium, whether tissue was adequate or not sufficient (scanty) for a histopathological diagnosis. The reports from pipelle aspiration and hysteroscopic directed biopsy are compared.

Results & Analysis

RESULT AND ANALYSIS

TABLE 3: AGE GROUP

Age in years	Number of patients (n=130)	Percent
40-44	43	33.1
45-49	61	46.9
50 and above	26	20
Total	130	100

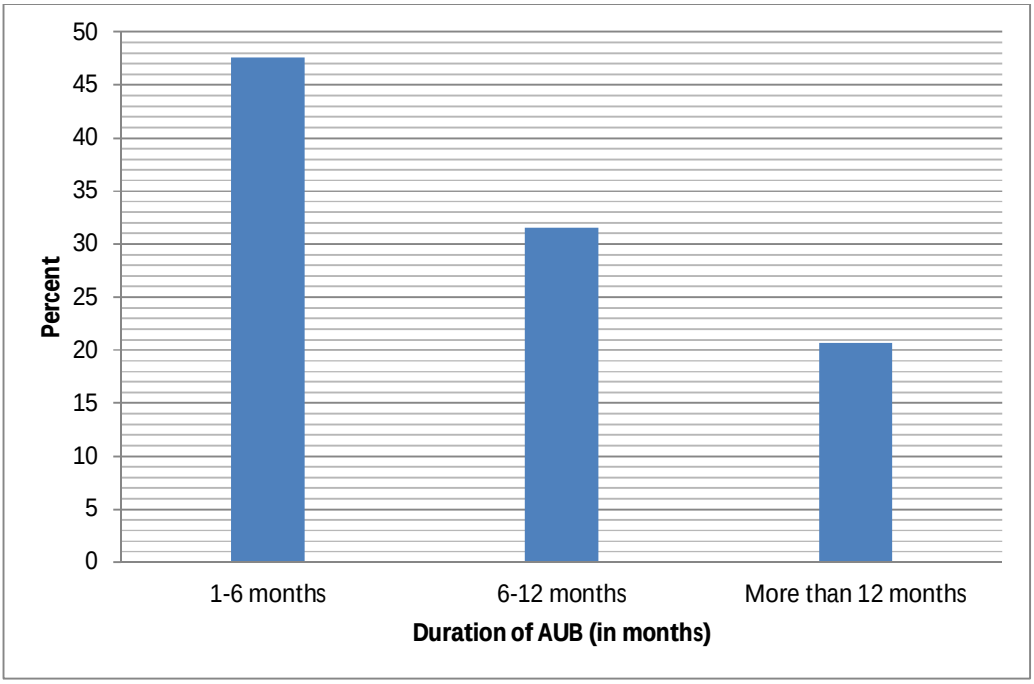


GRAPH 1: AGE GROUP

Of the 130 patients, the maximum number of patients (46.9%) were noted in the age group of 45-49 years, followed by 33.1% in the age group 40-44 years. 20% of the study subjects were in the age group of 50 years and above.

TABLE 4: DURATION OF AUB (IN MONTHS)

Duration of AUB \(in months)	Number of patients (n=130)	Percent
1-6 months	62	47.6
6-12 months	41	31.5
More than 12 months	27	20.7
Total	130	100

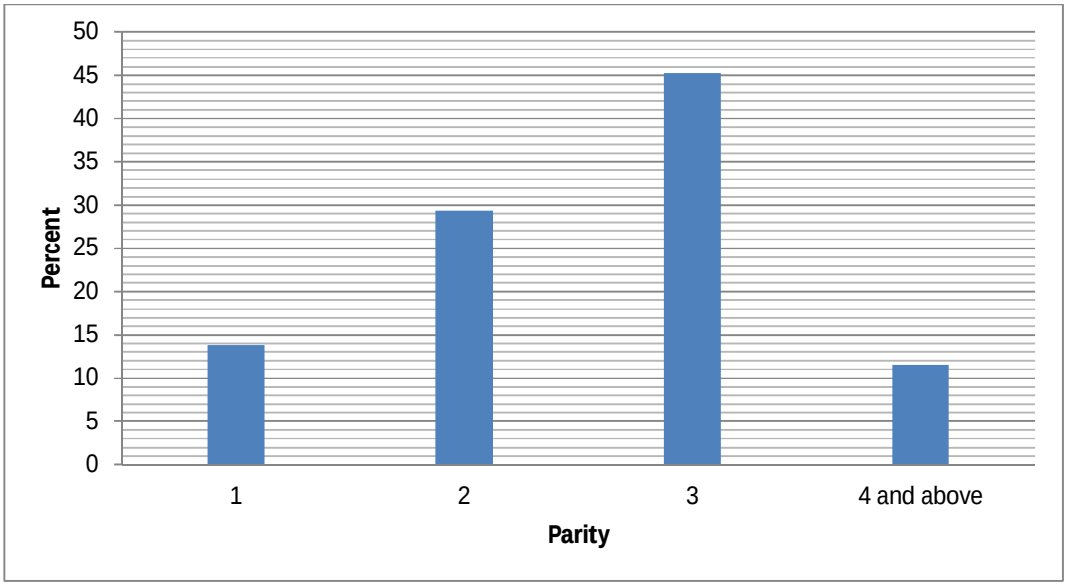


GRAPH 2: DURATION OF AUB (IN MONTHS

Majority of the patients (47.6%) presented within 6 months of onset of symptoms. 31.5% presented between 6 – 12 months and 20.7% presented after 12 months of onset of symptoms.

TABLE 5: NO. OF CHILDREN

No. of children	No.	Percent
1	18	13.8
2	38	29.4
3	59	45.3
4 and above	15	11.5
Total	130	100

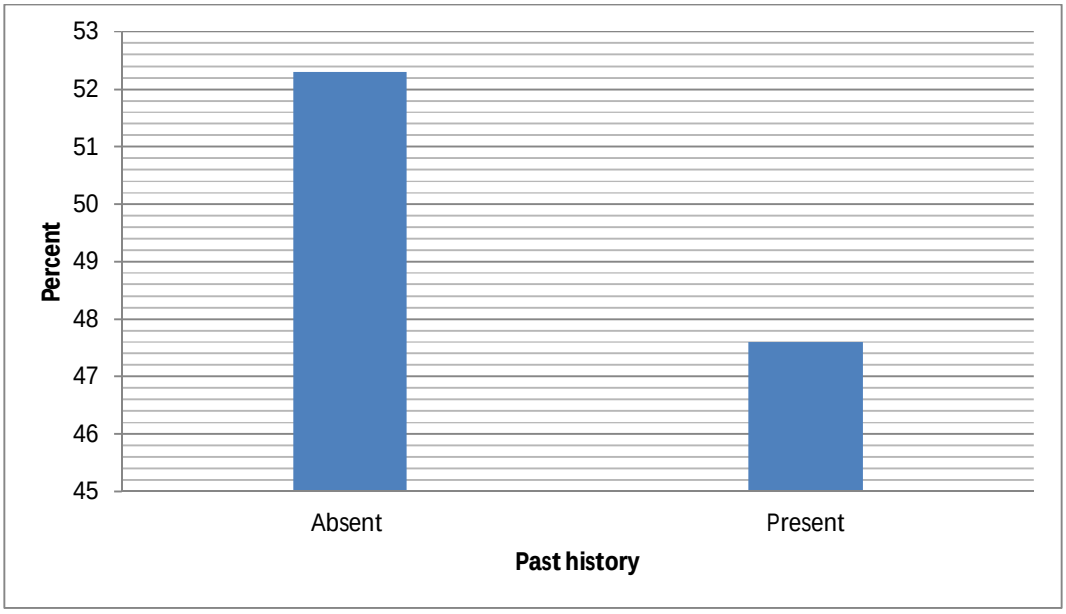


GRAPH 3: NO. OF CHILDREN

Multiparous women especially 3 and above were most commonly affected. Nulliparous women are not included in the study.

TABLE 6: PAST HISTORY

Past history	Number of patients (n=130)	Percent
Absent	68	52.3
Present	62	47.6
Total	130	100

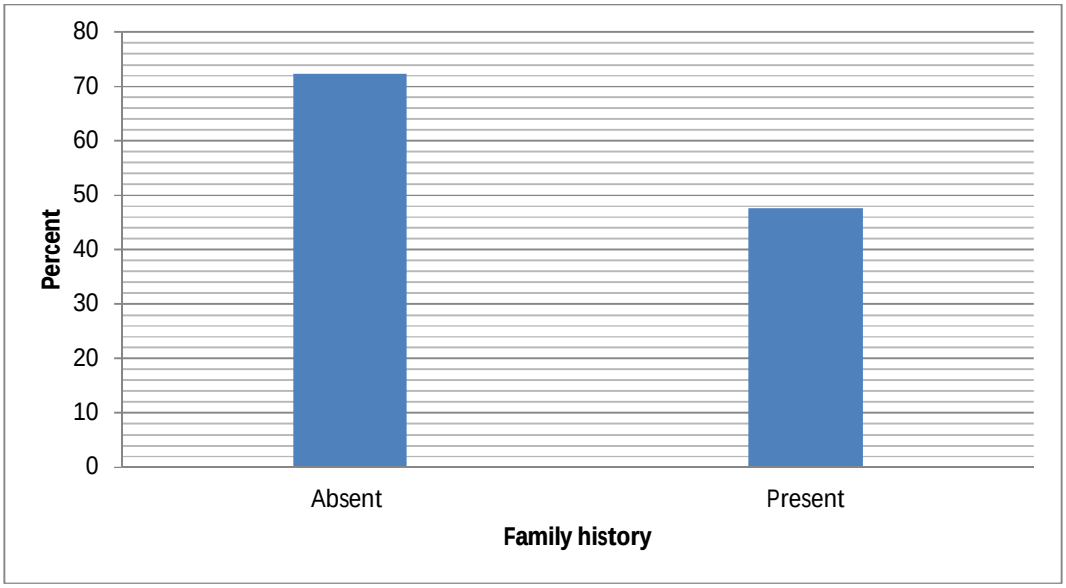


GRAPH 4: PAST HISTORY

Of the 130 patients there was a past history of some medical illnesses noted in 47.6% of the subjects. Hypertension was the commonest of the medical illnesses noted, accounting to 29%, followed by Diabetes mellitus in 12.2% who were in some form of treatment at the time of admission. Combination of medical illnesses were noted in 10 patients. 1 patient had history of epilepsy and 1 patient had pulmonary tuberculosis, but both were not on any medication at the time of admission.

TABLE 7: FAMILY HISTORY

Family history	Number of patients (n=130)	Percent
Absent	94	72.3
Present	36	27.6
Total	130	100

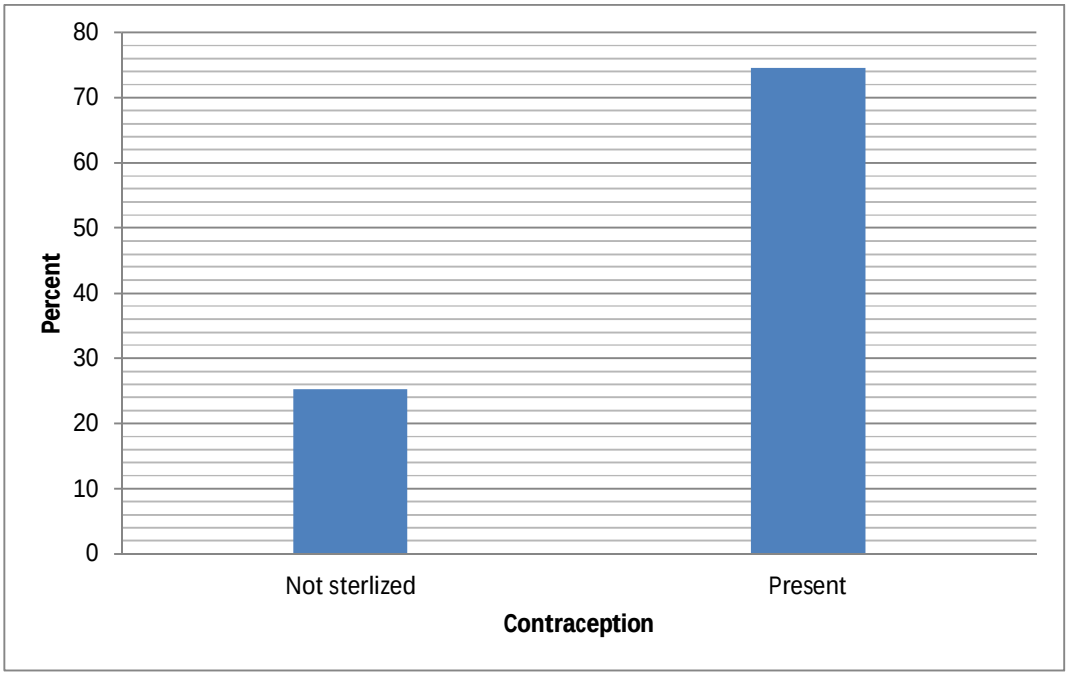


GRAPH 5: FAMILY HISTORY

There were no family history of any significant medical illnesses in 72.3% of the cases where as 27.6% of patients had family history of some medical illnesses. Hypertension, Diabetes mellitus, was most commonly noted in this group. Fibroid uterus(2%), Carcinoma colon(1%), Carcinoma lung(1%) was also noted in a first degree family relative in this group. Of the patient with family history of carcinoma colon (postmenopausal,ET=4) & carcinoma lung (premenopausal,ET=15), the HPE report was atrophic endometrium and simple hyperplasia without atypia respectively

TABLE 8: CONTRACEPTION

Contraception	Number of patients (n=130)	Percent
Not sterlized	33	25.3
Sterilized	97	74.6
Total	130	100

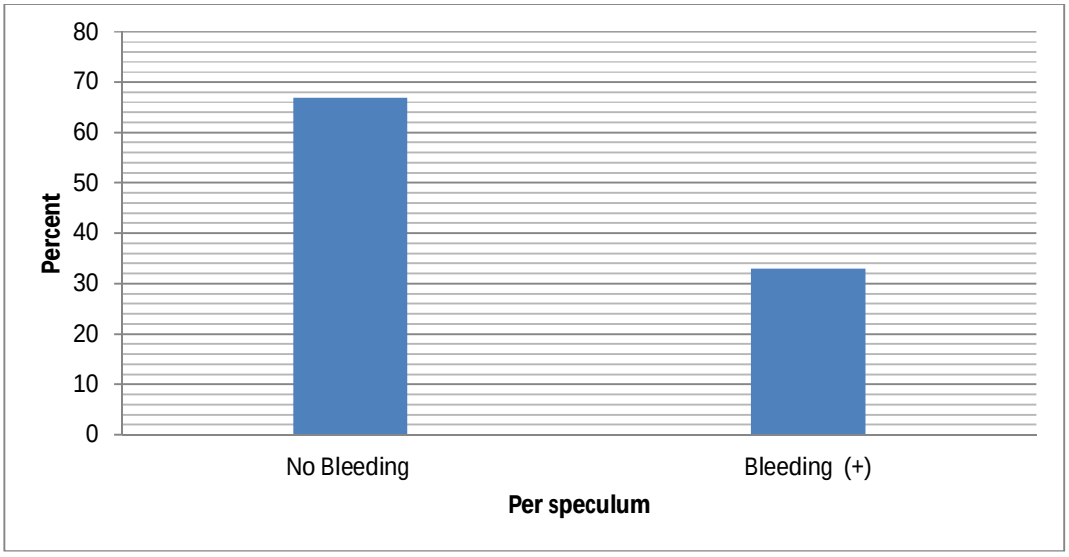


GRAPH 6: CONTRACEPTION

Of the study group, 25.3% of patients were not sterilized and 74.6% were sterilized. None of the patients were using additional contraceptive methods other than barrier methods at the time of admission. Less than 10% of patients had history of IUD use in the past.

TABLE 9: PER SPECULUM

Per speculum	Number of patients (n=130)	Percent
No Bleeding	87	66.9
Bleeding	43	33
Total	130	100

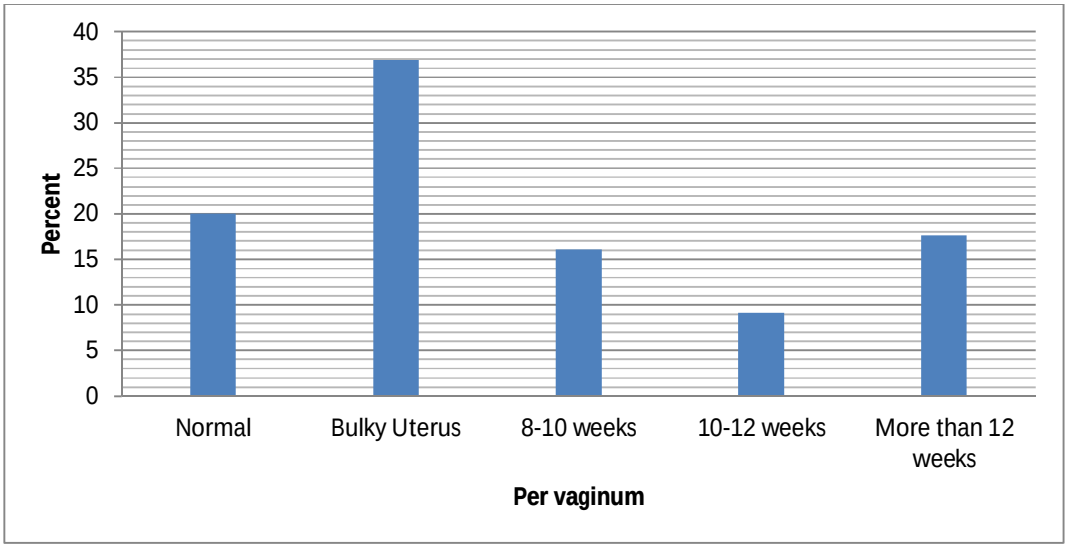


GRAPH 7: SPECULUM EXAMINATION

On per speculum examination,at the time of admission, cervix appeared grossly healthy in all subjects. Pap smear was taken for all subjects. Colposcopic biopsy was done in indicated cases. Ectropion-cervix was noted in 19% of the subjects. 33% of patients had bleeding at the time of examination (4 of 6 scanty HPE reports by both Pipelle and hysteroscopy had bleeding at the time of admission).

TABLE 10: PER VAGINUM

Per vaginum	Number of patients (n=130)	Percent
Normal	26	20
Bulky Uterus	48	36.9
8-10 weeks	21	16.1
10-12 weeks	12	9.2
More than 12 weeks	23	17.6
Total	130	100

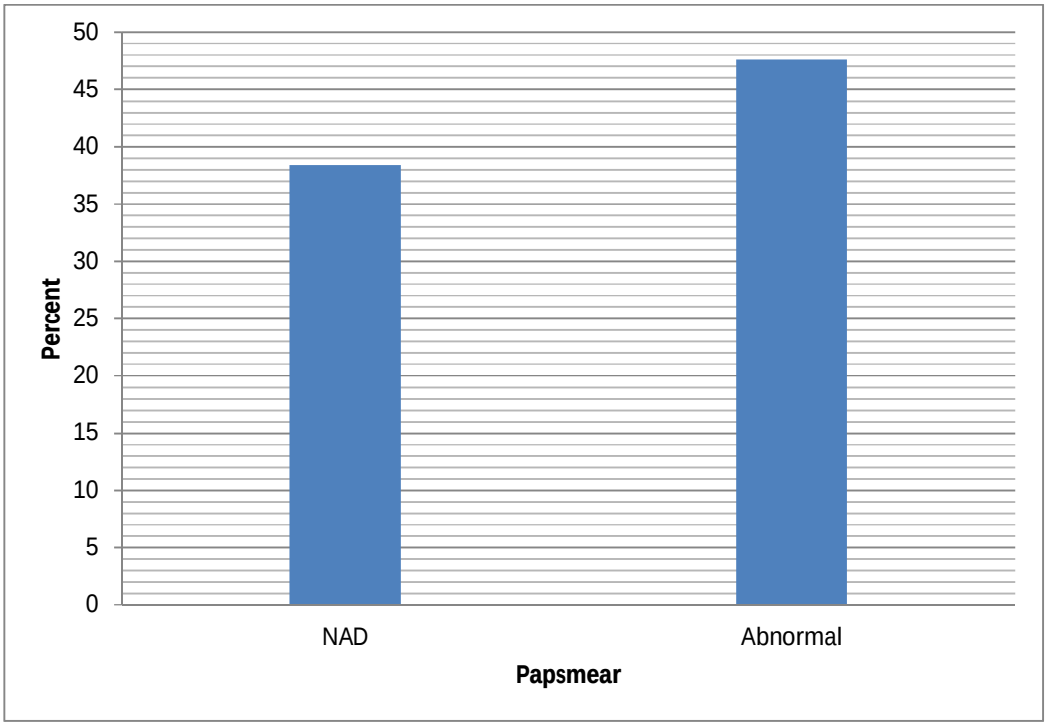


GRAPH 9 :PER VAGINUM EXAMINATION

Of the 130 patients, 20% patients had normal size uterus. 36.9% had bulky uterus, 16.1% had 8 – 10 weeks size uterus, 9.2% had 10 – 12 weeks size uterus and 17.6% had more than 12 weeks size uterus.

TABLE 11: PAPSMEAR

Papsmear	Number of patients (n=130)	Percent
NAD	50	38.4
Abnormal	80	61.5
Total	130	100



GRAPH 10: PAP SMEAR

Of the 130 patients in the study group, 38.4% had no abnormality detected in Papsmear, where as some abnormality was detected in 61.5% .

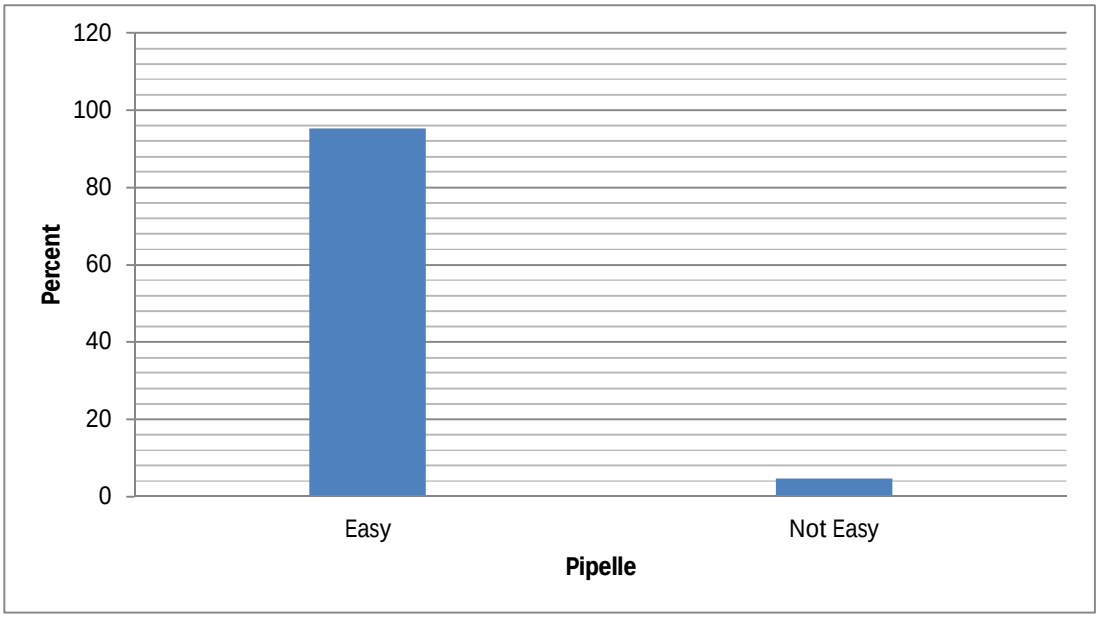
TABLE 12 : ABNORMAL PAPSMEAR

Abnormal Papsmear	Number of patients (n=80)
Inflammatory	76
ASCUS	3
LSIL	1

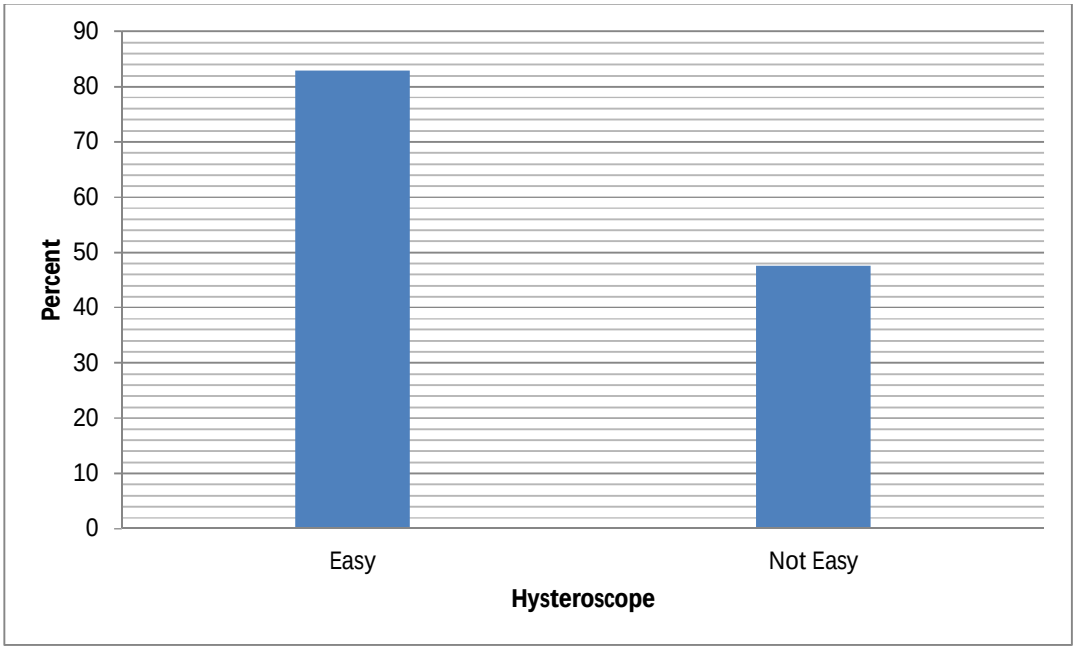
Of the abnormal Pap smears, inflammatory Papsmears were seen in 76 patients, ASCUS – 3 patients and LSIL - 1 patient. Cervical biopsy was done in indicated cases and no malignancies were found.

TABLE 13 : SAMPLING PROCEDURE

	Number of patients (n=130)	Percent
Sampling Procedure		
Pipelle		
• Easy	124	95.3
• Not Easy	6	4.6
Hysteroscope		
• Easy	108	83
• Not Easy	22	16.9



GRAPH 11: SAMPLING PROCEDURE - PIPELLE

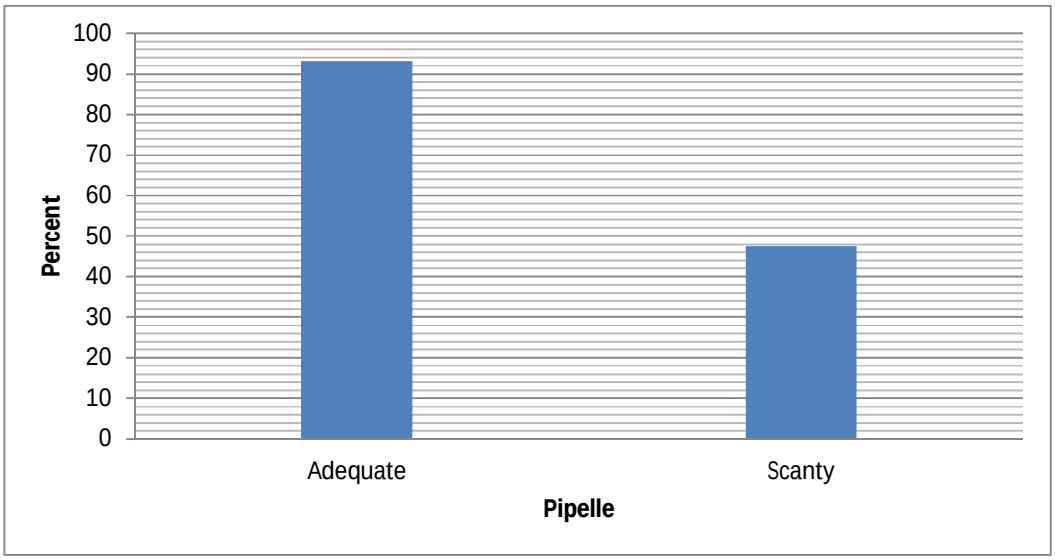


GRAPH 12: SAMPLING PROCEDURE - HYSTEROSCOPE

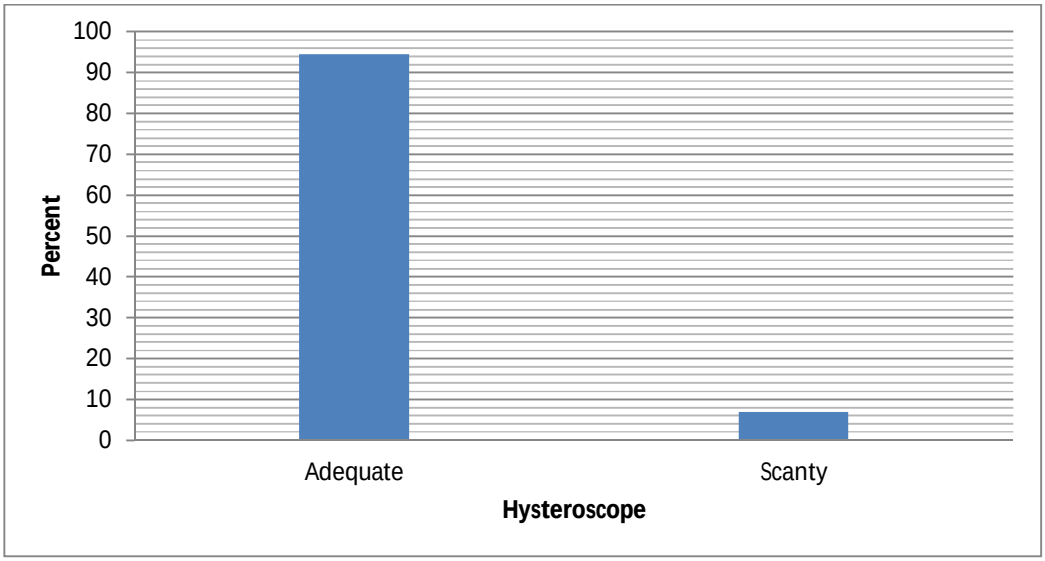
The percentage of patients in which pipelle was termed not easy was 4.6% when compared to 16.9% in hysteroscopy. Applying the Fischers exact test; the sensitivity, specificity, positive predictive value and negative predictive value of ease of procedure of pipelle endometrial sampling vs hysteroscope was calculated and was found to be as follows: Sensitivity=100 %, Specificity =8.3%, Positive predictive value=88.9 %, Negative predictive value =100%. The calculated p value is 0.125 which is statistically not significant. Thus comparing the ease of Pipelle procedure with hysteroscope, though 22 cases of hysteroscope were termed not easy compared to 6 by Pipelle, that was not statistically significant.

TABLE 14: TISSUE ADEQUACY

Tissue adequacy	Number of patients (n=130)	Percent
Pipelle		
• Adequate	121	93
• Scanty	9	6.9
Hysteroscope		
• Adequate	123	94.6
• Scanty	7	5.3



GRAPH 13: TISSUE ADEQUACY – PIPELLE

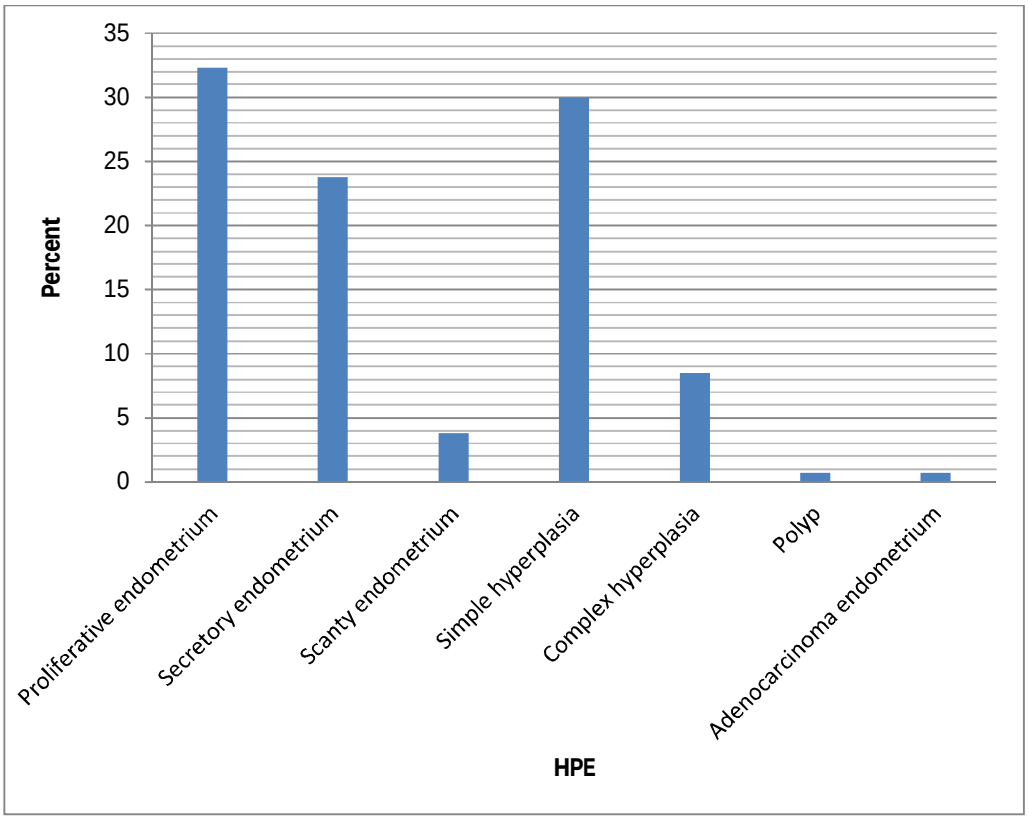


GRAPH 14: TISSUE ADEQUACY - HYSTEROSCOPE

Of the 130 subjects, scanty tissue was reported by the pathologist in 5.3% of the cases in hysteroscope group. 6.9% of pipelle sample was scanty. Of 130 cases, in 4.6% there was no histopathology reported due to scanty endometrium. Though the procedure was perceived as easy, sufficient sample was not obtained in 6 pipelle sample.

TABLE 15 : TYPE OF ENDOMETRIUM IN SAMPLE USING PIPELLE

HPE of pipelle sample	Number of patients (n=130)	Percent
Proliferative endometrium	42	32.3
Secretory endometrium	31	23.8
Scanty endometrium	5	3.8
Simple hyperplasia	39	30
Complex hyperplasia	11	8.5
Polyp	1	0.7
Adenocarcinoma endometrium	1	0.7
Total	130	100

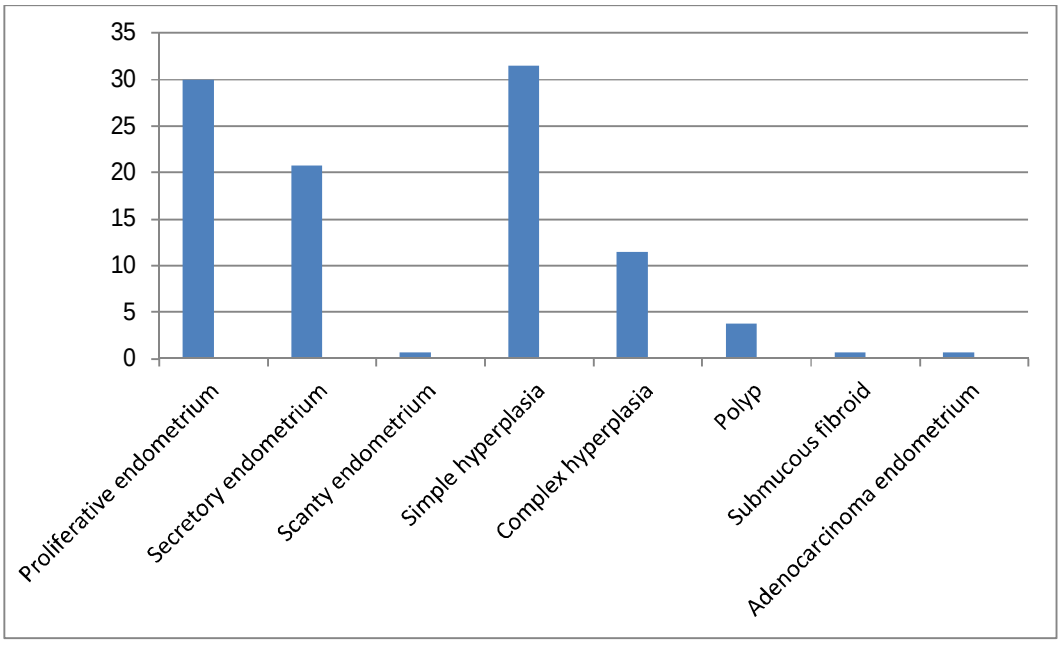


GRAPH 15: TYPE OF ENDOMETRIUM IN SAMPLE USING PIPELLE

The sample was sufficient in 94.6% of patients in hysteroscope sampling and 93% ofpatients in Pipelle sampling. The types of endometrium according to histopathology report obtained from pipelle aspiration consisted of proliferative phase, secretory phase, scanty endometrium, hyperplasia (simple, complex with/without atypia), and carcinoma (adenocarcinoma). The most common endometrial pattern identified was proliferative phase endometrium (32.3%). Simple hyperplasia of endometrium was second most common (30%) followed by secretary endometrium (23.8%), complex hyperplasia (8.5%), scanty endometrium (3.8%), polyp (0.7%) and endometrial carcinoma (0.7%).

TABLE 16: TYPE OF ENDOMETRIUM IN SAMPLE FROM HYSTEROSCOPIC DIRECTED BIOPSY

HPE of pipelle sample	Number of patients (n=130)	Percent
Proliferative endometrium	39	30
Secretory endometrium	27	20.7
Scanty endometrium	1	0.7
Simple hyperplasia	41	31.5
Complex hyperplasia	15	11.5
Polyp	5	3.8
Submucous fibroid	1	0.7
Adenocarcinoma endometrium	1	0.7
Total	130	100

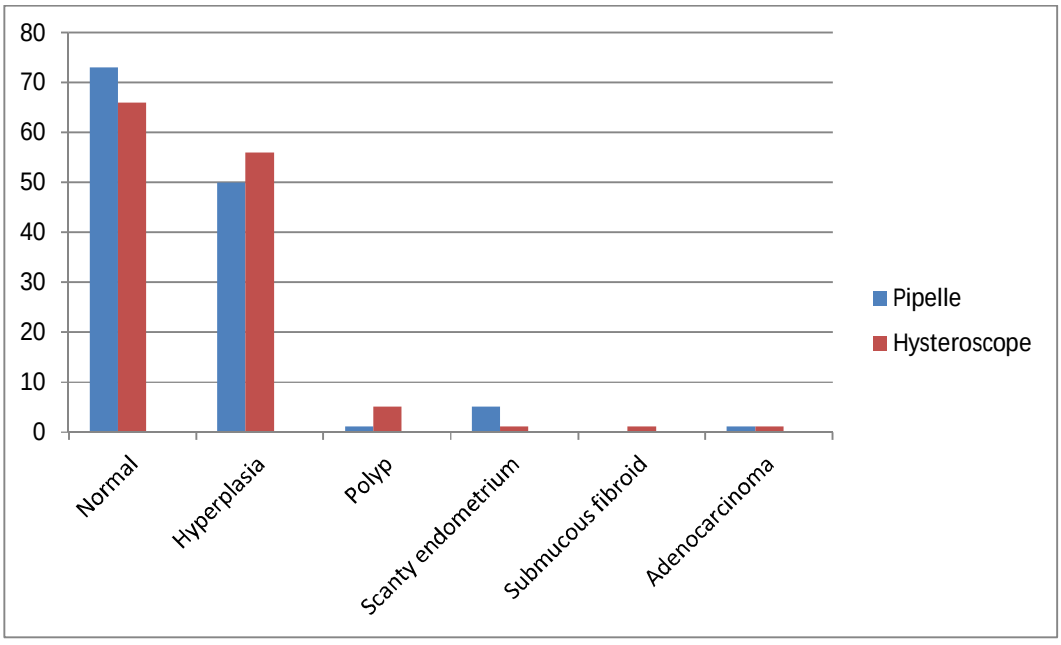


GRAPH 16: TYPE OF ENDOMETRIUM IN SAMPLE FROM HYSTEROSCOPIC DIRECTED BIOPSY

Histopathology report of hysteroscopic directed biopsy showed proliferative phase endometrium (30%), secretary endometrium (20.7%), simple hyperplasia of endometrium (31.5%) complex hyperplasia (11.5%), scanty endometrium (0.7%), polyp (3.8%), submucous fibroid (0.7%) and endometrial carcinoma (0.7%).

TABLE 17: COMPARISON OF THE PATHOLOGICAL DIAGNOSIS OF ENDOMETRIUM SAMPLED BY PIPELLE ASPIRATION AND HYSTEROSCOPIC DIRECTED BIOPSY

	Pipelle	Hysteroscope
Normal	73	66
Hyperplasia	50	56
Polyp	1	5
Scanty endometrium	5	1
Submucous fibroid	0	1
Adenocarcinoma	1	1
Total	130	130



GRAPH 17 : COMPARISON OF THE PATHOLOGICAL DIAGNOSIS FROM PIPELLE & HYSTEROSCOPE

TABLE 18: PIPELLE VS HYSTEROSCOPY:

Hysteroscope		Normal	Hyper plasia	Polyp	Adeno carcinoma	Scanty endometrium
Normal	66	66				
Hyperplasia	56	3	50			3
Polyp	5	4		1		
Submucous fibroid	1					1
Adenocarcinoma	1				1	
Scanty endometrium	1					1

Pipelle was able to diagnose all the normal histopathologic findings (66 patients), but it underdiagnosed 7 patients having hyperplasia and polyp as normal. Out of the 56 cases of hyperplasia, 50 cases was diagnosed correctly by pipelle. Remaining 3 was diagnosed as normal and 3 as scanty endometrium. Of the 5 polyps, only 1 was diagnosed correctly but 4 were labelled as normal. But pipelle missed the submucous fibroid that was diagnosed by hysteroscopy. Pipelle correctly diagnosed 1 patient with adenocarcinoma.

TABLE 19 : STATISTICAL ANALYSIS

Hysteroscope		**Abnormal**	**Normal**
Normal	60	53	7
Abnormal	70	4	66
		57	73

- Sensitivity = 93%
- Specificity = 90%
- Positive predictive value = 88%
- Negative predictive value = 94%

The results were analyzed using chi-square test and frequency & percentage analysis where histopathology of Pipelle's and Hysteroscopy guided biopsy were compared. There was statistically significant correlation between Pipelle & Hysteroscopy with a p value of 0.000.

TABLE 20: HPEPIPELLE * HPEHYSTEROSCOPY CROSSTABULATION									
Hpe Pipelle		Hpe Hysteroscopy							Total
		.00	Normal	Hyperplasia	Polyp	Adenocarcinoma	Scanty Endometrium	submucous fibroid	
.00	Count	1	0	0	0	0	0	0	1
	Expected Count	.0	.5	.4	.0	.0	.0	.0	1.0
Normal	Count	0	66	7	0	0	0	0	73
	Expected Count	.6	37.1	30.9	2.8	.6	.6	.6	73.0
Hyperplasia	Count	0	0	48	0	0	0	1	49
	Expected Count	.4	24.9	20.7	1.9	.4	.4	.4	49.0
polyp	Count	0	0	0	1	0	0	0	1
	Expected Count	.0	.5	.4	.0	.0	.0	.0	1.0
Adeno carcinoma	Count	0	0	0	1	0	0	0	1
	Expected Count	.0	.5	.4	.0	.0	.0	.0	1.0
Scanty Endometrium	Count	0	0	0	3	1	1	0	5
	Expected Count	.0	2.5	2.1	.2	.0	.0	.0	5.0
Total	Count	1	66	55	5	1	1	1	130
	Expected Count	1.0	66.0	55.0	5.0	1.0	1.0	1.0	130.0

TABLE 21: CHI-SQUARE TESTS			
	Value	df	Asymp. Sig. (2-sided)
Pearson Chi-Square	383.713[a]	30	.000
Likelihood Ratio	190.228	30	.000
Linear-by-Linear Association	83.351	1	.000
N of Valid Cases	130		

a. 38 cells (90.5%) have expected count less than 5. The minimum expected count is .01.

TABLE 22: SYMMETRIC MEASURES					
		Value	Asymp. Std. Error[a]	Approx. T[b]	Approx. Sig.
Interval by Interval	Pearson's R	.804	.083	15.288	.000[c]
Ordinal by Ordinal	Spearman Correlation	.912	.030	25.096	.000[c]
N of Valid Cases		130			

a. Not assuming the null hypothesis.

b. Using the asymptotic standard error assuming the null hypothesis.

c. Based on normal approximation

Pipelle Curette & hysteroscopy are able to obtain statistically significant results in the detection of abnormalities of the uterus in cases of perimenopausal bleeding.

Discussion

DISCUSSION

This prospective descriptive comparative study analyzing the role of Pipelle aspiration in diagnosing endometrial pathology perimenopausal women with abnormal uterine bleeding (AUB) was undertaken in 130 patients.

The results of this study are discussed below:

Characteristics of the study group:

TABLE 3: Most of the patients in this study belonged to the age group of 45-49 years accounting for 46.9%.

TABLE 4: Majority of the patients (47.6%) presented to the OPD within 6 months of onset of symptoms.

TABLE 5: Patients were selected irrespective of their parity, but multiparous women with parity 3 and above are more commonly affected (56.8%)

TABLE 6 & 7: Past history of medical illnesses was present in 53.2% of the subjects while family history was present in 27.6%

TABLE 8: 74.6% of the patients were sterilised.

TABLE 9: Per speculum examination showed bleeding in 33% of the patients.

TABLE 10: On per vaginal examination, uterus was bulky was 36.9%, normal size in 20%, more than 12 weeks size in 17.6%, 8 – 10 weeks size in 16% and 10 – 12 weeks size in 9.2%.

TABLE 11 & 12: Pap smear was abnormal in 61.5% of the patients , inflammatory smears corresponding to the major proportion.

TABLE 13: Sampling with pipelle was easy in 95.3% of the subjects while it was easy in only 83% of the subjects with hysteroscope.

TABLE 14: Tissue was adequate in 93% of the patients sampled using pipelle while hysteroscope gave an adequate tissue in 94.6% of the patients.

TABLE 15: In the present study, abnormal findings like hyperplasia, polyp and malignancy were noted in 57 patients (43.8%) while the remaining 56.2%of the patients had a normal endometrium either proliferative or secretory. Pipelle succeded in diagnosing the one case of adenocarcinoma as hysteroscopy.

Manganiello et al in Lebanon proved that Pipelle obtained adequate samples in 78 of 79 cases (98.7%) which is similar to our study where the inconclusive reports were due to scanty samples in 3.8%

Critchley HO et al in UK also proved that Pipelle biopsy could obtain adequate endometrial sample in low risk women of perimenopausal age (79%) compared to high-risk postmenopausal women (43%) Guido et al did Pipelle biopsies in 65 patients and found that adequate tissue for analysis was obtained in 97%. Ben Baruch et al in Israel at the same time proved that sufficient endometrial sample was obtained in 90.6% of women and the discomfort caused was only very slight. Guido and associates found that Pipelle missed 3 of the 5 polyps and a sub mucous fibroid and hence concluded "Pipelle is excellent for detecting global processes of the endometrium than focal lesions." The results were same in our study where Pipelle missed 4 of the 6 polyps. Bunyavejchevin S et al in Thailand showed the sensitivity and specificity of Pipelle in endometrial tissue sampling to be 87.5% and 100%

TABLE 16 : 49% of the patients were found to have some abnormality in hysteroscope such as polyp, hyperplasia and sub mucous fibroid. 51% of the patient had normal findings.

One case of submucous fibroid that was missed by pipelle was diagnosed by hysteroscopy. Hysteroscope diagnosed all 5 cases of polyp while pipelle diagnosed only 1 of them.

In our study, hysteroscopic guided biopsy showed a sensitivity of 100% and specificity of 91% in the detection of abnormal uterine finding with a positive predictive value of 98% and a negative predictive value of 100%

The values are comparable with other reports in the literature such as Torrejon R, Cominor et al in Spain who showed the sensitivity, specificity and the global diagnostic precision as 100%, 99.4% and 99.5% respectively.

Altaras MM, Aviram R et al also in their study proved the sensitivity and positive predictive value as 93.7% and 83.3% respectively which is similar to our study.

Garuti G et al at Italy when estimating the accuracy of hysteroscopy found it to be greatest in polyps comparable to our study. The sensitivity & specificity were 94.3% and 88.8% respectively. Wit AC and Vlengels MP in Netherlands concluded that hysteroscopy is a valuable tool in diagnosing structural intracavitary pathology.

In this study, hysteroscopy was able to detect uterine cavity abnormalities with a correct diagnosis in 98% of the cases.

TABLE 17 - 22 : These tables compare the statistical correlation between pipelle and hysteroscopy. There was statistically significant correlation between Pipelle & Hysteroscopy with a p value of 0.000. respectively whereas the results in this study is 72% and 100% Van den Bosch et al in South Africa came out with data which favor Pipelle as an initial diagnostic tool with a specificity .

Summary

SUMMARY

This present descriptive prospective study analyzing the role of endometrial sampling as an outpatient procedure using Pipelle in perimenopausal women with AUB was carried out at Institute of Obstetrics and Gynaecology,Madras Medical College, Chennai during the period October 2014 to September 2015. A total of 130 patients were included in the study. All the patients underwent an initial examination using Pipelle's curette followed by hysteroscopy guided biopsy.

Observations in this study includes

- Patients in the study group were 40 years and above with 47% of them belonging to the 45 – 49 age group.
- The study encompasses women of any parity but excludes nulliparous women.
- Majority of patients (47%) had presented within 6 months of onset of symptoms.
- Both Pipelle's curette and hysteroscopic biopsy produced statistically significant results while investigating perimenopausal bleeding. (p =0.000).

- When histopathology of the endometrium was obtained using Pipelle's curette, correct diagnosis could be obtained in 93% of the cases.
- Similarly when hysteroscopy was performed the correct diagnosis was98%
- Pipelle showed a sensitivity of 93%, specificity of 90% in the detection of abnormal findings with PPV of 88% and NPV of 94%.
- However accuracy of pipelle is found to be less in the diagnosis of polyps and submucous fibroids with accuracy of less than 100%.

Conclusion

CONCLUSION

Endometrial sampling using Pipelle is an easy, effective and safe method for obtaining endometrial tissue for diagnosis in patients with abnormal uterine bleeding. It can be done as an outpatient procedure. Moreover, it is cost effective, is minimally invasive procedure and has better patient compliance in addition to the added advantage of no use of anesthesia or other procedure complications like perforation compared to hysteroscopy.

It can be considered as the first line investigation for obtaining an adequate endometrial sample for histology in patients with AUB with high sensitivity and specificity even for the detection of hyperplasia and malignancy. Thus pipelle has a central role for Endometrial Sampling as an Outpatient (ESOP) procedure for abnormal uterine bleeding in perimenopausal women according to the new guidelines for the management of Dysfunctional Uterine Bleeding, before considering any other diagnostic modalities. Therefore it is essential to broaden its use and include it in the routine diagnostic modalities.

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Annexures

PROFORMA

NAME **AGE** **IPNO** **SES**

PARA LIVE ABORTIONS

COMPLAINTS

H/o Abnormal bleeding – type

Duration

Cycles

LMP

H/o Pain abdomen

H/o White discharge - Scanty / profuse / blood stained / itchy / foul smelling

H/o intermenstrual bleeding

H/o postcoital bleeding

H/o burning micturition

Menopause

PREVIOUS MENSTRUAL HISTORY :

MARITAL HISTORY :

PAST HISTORY :

PERSONAL HISTORY :

FAMILY HISTORY :

TREATMENT HISTORY :

CONTRACEPTION : Yes / No

Type

Duration

GENERAL EXAMINATION

HEIGHT WEIGHT BMI

ABDOMEN EXAMINATION :

SPECULUM EXAMINATION :

PERVAGINAL EXAMINATION :

PROVISIONAL DIAGNOSIS :

INVESTIGATIONS :

Urine Albumin

Urine Sugar

Urine Deposits

Blood Hb

Chest X-ray

ECG

PIPELLE ASPIRATION SAMPLING

TECHNIQUE EASY/ NOT EASY

SAMPLE ADEQUATE/ INADEQUATE

HPE :

HYSTEROSCOPY :

TECHNIQUE EASY/ NOT EASY

SAMPLE ADEQUATE/ INADEQUATE

DISTENSION MEDIA :

TYPE OF ANESTHESIA :

NEED FOR DILATATION :

ENDOCERVICAL CANAL :

ENDOMETRIUM :

OSTIA :

VASCULAR PATTERN :

POLYP :

COLOR OF ENDOMETRIUM :

HPE:

Master Chart

S. No	I.P. No	Age	AUB Duration	LMP	Party Index	Past History	Family History	Per abdomen	Per Speculum	Per vaginium	PAP smear	TAS ET (mm)	Sampling Procedure		Tissue adequacy		HPE
													Pipelle	Hysteroscopy directed biopsy	Pipelle	Hysteroscopy directed biopsy	
1	1001	43	2 month	1. 10.13	P_3L_3	DM	NS	NO MASS	NAD	UTERUS-NS	NAD	8	Easy	Easy	Adq	Adq	Secretory endometrium
2	1008	42	1 month	3.10.13	P_4L_4	HTN	NS	NO MASS	NAD	UTERUS-NS	INFLAMATORY	4	Not easy	Easy	Adq	Adq	Secretory endometrium
3	1200	45	3 month	5.10.13	P_3L_3	NS	FATER-HTN	NO MASS	BLEEDING +	UTERUS-BULKY	INFLAMATORY	6	Easy	Not easy	Adq	Adq	Proliferative endometrium
4	1208	45	5 month	21.11.13	P_3L_3	Anemia	NS-SISTER HTN	NO MASS	NAD	UTERUS-NS	INFLAMATORY	6	Not easy	Easy	Adq	Scanty	Secretory endometrium
5	1305	40	6 month	22.11.13	P_2L_2	NS	FATHER-CO-COLON	NO MASS	NAD	UTERUS-NS	NAD	7	Easy	Easy	Adq	Adq	Proliferative endometrium
6	1456	41	8 month	24.11.13	P_4L_4	NS	NS	NO MASS	NAD	UTERUS-NS	INFLAMATORY	19	Easy	Easy	Adq	Adq	Proliferative endometrium
7	1567	41	11 month	25.11.13	Nullipara	NS	NS	NO MASS	NAD	UTERUS-BULKY	NAD	7	Easy	Easy	Adq	Adq	Secretory endometrium
8	1777	43	1 year	1.12.13	P_3L_3	HTN	NS	NO MASS	ECTROPION+	UTERUS-BULKY	INFLAMATORY	4	Easy	Easy	Adq	Adq	Atrophic endometrium
9	2001	40	2 month	2.12.13	P_3L_3	NS	NS	NO MASS	NAD	UTERUS-BULKY	INFLAMATORY	10	Easy	Easy	Adq	Adq	Irregular shedding
10	2398	40	3 month	3.12.13	P_2L_2	NS	NS	NO MASS	NAD	UTERUS-BULKY	INFLAMATORY	15	Not easy	Easy	Adq	Adq	Simple hyperplasia without atypia
11	2456	41	1 year	4.12.13	P_2L_2	DM	NS	NO MASS	NAD	UTERUS-BULKY	NAD	13	Easy	Easy	Adq	Adq	Proliferative endometrium
12	3009	41	1 month	5.12.13	P_6L_6	NS	MOTHER-HTN	NO MASS	NAD	UTERUS-BULKY	INFLAMATORY	10	Easy	Easy	Adq	Adq	Proliferative endometrium
13	3456	42	4 month	6.12.13	P_2L_2	HTN	NS	NO MASS	NAD	UTERUS-BULKY	NAD	15	Easy	Easy	Adq	Adq	Proliferative endometrium
14	4565	42	2 month	7.12.13	P_3L_3	NS	NS	NO MASS	NAD	UTERUS-BULKY	INFLAMATORY	15	Easy	Easy	Adq	Adq	Proliferative endometrium
15	5678	42	1 month	8.12.13	P_3L_3	NS	NS	NO MASS	NAD	UTERUS-BULKY	NAD	16	Easy	Easy	Adq	Adq	Secretory endometrium
16	7777	42	11 month	12.12.13	P_2L_2	Anemia	NS	NO MASS	NAD	UTERUS-NS	NAD	6	Not easy	Easy	Adq	Adq	Secretory endometrium
17	7995	45	1 year	15.12.13	P_2L_2	NS	NS	NO MASS	NAD	UTERUS-BULKY	NAD	14	Easy	Easy	Adq	Adq	Proliferative endometrium
18	8765	45	1 year	16.12.13	P_4L_4	NS	NS	NO MASS	NAD	UTERUS-BULKY	INFLAMATORY	10	Easy	Easy	Adq	Adq	Proliferative endometrium
19	9743	43	1 year	21.12.13	P_2L_2	NS	NS	NO MASS	NAD	UTERUS-BULKY	INFLAMATORY	8	Easy	Easy	Adq	Adq	Proliferative endometrium
20	10003	43	1 year	22.12.13	P_3L_3	DM	NS	NO MASS	BLEEDING +	UTERUS-BULKY	NAD	15	Easy	Easy	Adq	Adq	Simple hyperplasia without atypia
21	10005	43	2 month	25.12.13	P_3L_3	NS	NS	NO MASS	NAD	UTERUS-BULKY	INFLAMATORY	13	Easy	Easy	Adq	Adq	Proliferative endometrium

S. No	I.P. No	Age	AUB Duration	LMP	Party Index	Past History	Family History	Per abdomen	Per Speculum	Per vaginium	PAP smear	TAS ET (mm)	Sampling Procedure		Tissue adequacy		HPE
													Pipelle	Hysteroscopy directed biopsy	Pipelle	Hysteroscopy directed biopsy	
22	10007	43	3 month	1.01.14	P_5L_5	NS	NS	NO MASS	NAD	UTERUS-BULKY	INFLAMATORY	18	Easy	Easy	Adq	Adq	Secretory endometrium
23	10011	44	8 month	2.01.14	P_3L_3	HTN	NS	NO MASS	NAD	UTERUS-BULKY	INFLAMATORY	14	Easy	Easy	Scanty	Adq	Secretory endometrium
24	10034	44	11 month	3.01.14	P_4L_4	NS	NS	NO MASS	ECTROPION+	UTERUS-BULKY	NAD	16	Easy	Easy	Adq	Adq	Secretory endometrium
25	10111	44	2 month	4.01.14	P_3L_3	NS	NS	NO MASS	NAD	UTERUS-BULKY	INFLAMATORY	4	Not easy	Easy	Adq	Scanty	scanty endometrium
26	10121	44	4 month	5.01.14	P_4L_4	HTN	NS	NO MASS	NAD	UTERUS-BULKY	NAD	12	Easy	Easy	Adq	Adq	Secretory endometrium
27	10131	44	5 month	6.01.14	P_3L_3	HTN+DM	NS	NO MASS	NAD	UTERUS-NS	INFLAMATORY	14	Easy	Easy	Adq	Adq	Proliferative endometrium
28	10132	41	6 month	7.01.14	P_3L_3	NS	MOTHER-BA	NO MASS	NAD	UTERUS-NS	INFLAMATORY	12	Easy	Easy	Adq	Adq	Proliferative endometrium
29	10143	45	2 month	11.01.14	P_2L_2	NS	NS	NO MASS	NAD	UTERUS-BULKY	INFLAMATORY	8	Easy	Easy	Adq	Adq	Secretory endometrium
30	10145	45	1 month	12.01.14	P_4L_4	HTN	NS	NO MASS	NAD	UTERUS-NS	NAD	4	Easy	Easy	Adq	Adq	Secretory endometrium
31	10455	45	3 month	13.01.14	Nullipara	NS	MOTHER-DM	NO MASS	NAD	UTERUS-NS	INFLAMATORY	6	Easy	Easy	Adq	Adq	Proliferative endometrium
32	10457	45	5 month	15.01.14	P_3L_3	DM	NS	NO MASS	NAD	UTERUS-NS	NAD	6	Easy	Easy	Adq	Adq	Secretory endometrium
33	10458	45	6 month	01.02,14	P_3L_3	HTN	NS	NO MASS	NAD	UTERUS-BULKY	INFLAMATORY	7	Easy	Easy	Adq	Adq	Proliferative endometrium
34	10555	43	8 month	02.02.14	P_2L_2	NS	NS	NO MASS	NAD	UTERUS-BULKY	NAD	19	Easy	Easy	Adq	Adq	Secretory endometrium
35	10576	42	11 month	03.02.14	P_2L_2	Anemia	NS	NO MASS	BLEEDING+	UTERUS-BULKY	NAD	7	Easy	Easy	Adq	Adq	Proliferative endometrium
36	10657	45	1 year	05.02.14	P_6L_6	NS	NS	NO MASS	NAD	UTERUS-BULKY	NAD	4	Not easy	Easy	Adq	Adq	Secretory endometrium
37	10789	45	2 month	06.02.14	P_2L_2	NS	BROTHER-CA LUNG	NO MASS	NAD	UTERUS-BULKY	INFLAMATORY	10	Easy	Easy	Adq	Adq	Simple hyperplasia
38	10799	40	3 month	07.02.14	P_3L_3	NS	NS	NO MASS	NAD	UTERUS-BULKY	INFLAMATORY	15	Easy	Easy	Adq	Adq	Proliferative endometrium
39	10898	41	1 year	22.03.14	P_3L_3	HTN	NS	NO MASS	NAD	UTERUS-BULKY	NAD	13	Easy	Easy	Adq	Adq	Secretory endometrium
40	11001	41	1 month	24.03.14	P_2L_2	NS	NS	NO MASS	ECTROPION+	UTERUS-BULKY	INFLAMATORY	10	Easy	Easy	Adq	Adq	Proliferative endometrium
41	11003	43	4 month	25.03.14	P_2L_2	NS	NS	NO MASS	NAD	UTERUS-BULKY	INFLAMATORY	15	Easy	Easy	Adq	Adq	Secretory endometrium
42	11005	40	2 month	03.04.14	P_4L_4	DM	NS	NO MASS	NAD	UTERUS-NS	INFLAMATORY	15	Easy	Easy	Adq	Adq	simple hyperplasia
43	11006	40	1 month	05.04.14	P_2L_2	NS	NS	NO MASS	NAD	UTERUS-BULKY	NAD	16	Easy	Easy	Adq	Adq	Irregular shedding
44	11007	41	11 month	11.04.14	P_3L_3	HTN	NS	NO MASS	NAD	UTERUS-BULKY	INFLAMATORY	6	Easy	Easy	Scanty	Adq	Proliferative endometrium
45	11009	41	1 year	13.04.14	P_3L_3	NS	NS	NO MASS	NAD	UTERUS-BULKY	NAD	14	Easy	Easy	Adq	Adq	Irregular shedding
46	11012	42	1 year	15.04.14	P_5L_5	NS	NS	NO MASS	NAD	UTERUS-BULKY	INFLAMATORY	10	Easy	Easy	Adq	Adq	simple hyperplasia
47	11014	42	1 year	17.04.14	P_3L_3	Anemia	NS	NO MASS	NAD	UTERUS-BULKY	INFLAMATORY	8	Easy	Easy	Adq	Adq	Secretory endometrium
48	11015	42	1 year	21.04.14	P_4L_4	NS	NS	NO MASS	NAD	UTERUS-BULKY	INFLAMATORY	15	Easy	Easy	Adq	Adq	Secretory endometrium

S. No	I.P. No	Age	AUB Duration	LMP	Party Index	Past History	Family History	Per abdomen	Per Speculum	Per vaginium	PAP smear	TAS ET (mm)	Sampling Procedure		Tissue adequacy		HPE
													Pipelle	Hysteroscopy directed biopsy	Pipelle	Hysteroscopy directed biopsy	
49	11018	42	2 month	22.04.14	P_3L_3	NS	NS	NO MASS	NAD	UTERUS-BULKY	NAD	13	Easy	Easy	Adq	Adq	Secretory endometrium
50	11030	45	3 month	02.05.14	P_4L_4	NS	FATHER-BA,MOTHER-	NO MASS	NAD	UTERUS-BULKY	INFLAMATORY	18	Easy	Easy	Adq	Adq	Proliferative endometrium
51	11033	45	8 month	03.05.14	P_3L_3	DM	SISTER FIBROID – UTERUS	NO MASS	NAD	UTERUS-BULKY	NAD	14	Easy	Easy	Adq	Adq	Proliferative endometrium
52	11034	43	11 month	04.05.14	P_3L_3	NS	NS	NO MASS	BLEEDING +	UTERUS-BULKY	INFLAMATORY	16	Easy	Easy	Adq	Adq	Proliferative endometrium
53	11035	43	2 month	21.05.14	P_2L_2	NS	NS	NO MASS	NAD	UTERUS-NS	NAD	4	Easy	Easy	Adq	Adq	Proliferative endometrium
54	11046	43	4 month	22.05.14	P_4L_4	HTN	FATER-HTN	NO MASS	NAD	UTERUS-NS	NAD	12	Easy	Easy	Adq	Adq	Secretory endometrium
55	11066	43	5 month	03.06.14	Nullipara	NS	NS-SISTER HTN	NO MASS	NAD	UTERUS-BULKY	NAD	14	Easy	Easy	Adq	Scanty	scanty endometrium
56	11057	44	6 month	05.06.14	P_3L_3	NS	FATHER-CO-COLON	NO MASS	ECTROPION+	UTERUS-NS	INFLAMATORY	12	Easy	Easy	Scanty	Adq	scanty endometrium
57	11058	44	2 month	21.06.14	P_3L_3	HTN	NS	NO MASS	NAD	UTERUS-NS	INFLAMATORY	8	Easy	Easy	Adq	Adq	Secretory endometrium
58	11069	44	1 month	03.07.14	P_2L_2	HTN+DM	NS	NO MASS	NAD	UTERUS-NS	NAD	4	Easy	Easy	Adq	Adq	Secretory endometrium
59	11054	44	3 month	06.07.14	P_2L_2	NS	NS	NO MASS	NAD	UTERUS-BULKY	INFLAMATORY	6	Easy	Easy	Adq	Adq	Secretory endometrium
60	11057	44	5 month	08.07.14	P_6L_6	NS	NS	NO MASS	NAD	UTERUS-BULKY	INFLAMATORY	6	Easy	Easy	Adq	Adq	Proliferative endometrium
61	11076	41	6 month	11.07.14	P_2L_2	HTN	NS	NO MASS	NAD	UTERUS-BULKY	INFLAMATORY	7	Easy	Easy	Adq	Adq	Proliferative endometrium
62	11068	45	8 month	13.07.14	P_3L_3	NS	NS	NO MASS	NAD	UTERUS-BULKY	NAD	19	Easy	Easy	Adq	Adq	Proliferative endometrium
63	12001	45	11 month	21.07.14	P_3L_3	DM	MOTHER-HTN	NO MASS	NAD	UTERUS-BULKY	INFLAMATORY	7	Easy	Easy	Adq	Adq	Secretory endometrium
64	12003	45	1 year	22.07.14	P_2L_2	HTN	NS	NO MASS	NAD	UTERUS-BULKY	NAD	4	Easy	Easy	Adq	Adq	Secretory endometrium
65	12004	45	2 month	01.08.14	P_2L_2	NS	NS	NO MASS	NAD	UTERUS-BULKY	INFLAMATORY	10	Easy	Easy	Scanty	Adq	Secretory endometrium
66	12007	45	3 month	22.08.14	P_4L_4	Anemia	NS	NO MASS	NAD	UTERUS-BULKY	INFLAMATORY	15	Easy	Easy	Scanty	Adq	Proliferative endometrium
67	12009	43	1 year	23.08.14	P_2L_2	NS	NS	NO MASS	BLEEDING	UTERUS-BULKY	INFLAMATORY	13	Easy	Easy	Adq	Adq	Secretory endometrium
68	13001	42	1 month	24.08.14	P_3L_3	NS	NS	NO MASS	NAD	UTERUS-NS	NAD	10	Easy	Easy	Adq	Adq	Proliferative endometrium
69	13004	45	4 month	25.08.14	P_3L_3	NS	NS	NO MASS	NAD	UTERUS-BULKY	INFLAMATORY	15	Easy	Easy	Adq	Adq	Proliferative endometrium
70	13005	45	2 month	02.09.14	P_5L_5	HTN	NS	NO MASS	NAD	UTERUS-BULKY	NAD	15	Easy	Easy	Adq	Adq	Secretory endometrium
71	13007	40	1 month	03.09.14	P_3L_3	NS	NS	NO MASS	NAD	UTERUS-BULKY	INFLAMATORY	16	Easy	Easy	Adq	Adq	Atrophic endometrium
72	13009	41	11 month	05.09.14	P_4L_4	NS	NS	NO MASS	ECTROPION+	UTERUS-BULKY	NAD	6	Easy	Easy	Adq	Adq	Irregular shedding
73	13010	41	1 year	07.09.14	P_3L_3	DM	NS	NO MASS	NAD	UTERUS-BULKY	NAD	14	Easy	Easy	Adq	Adq	Simple hyperplasia without atypia

S. No	I.P. No	Age	AUB Duration	LMP	Party Index	Past History	Family History	Per abdomen	Per Speculum	Per vaginium	PAP smear	TAS ET (mm)	Sampling Procedure		Tissue adequacy		HPE
													Pipelle	Hysteroscopy directed biopsy	Pipelle	Hysteroscopy directed biopsy	
74	13011	43	1 year	21.10.14	P_4L_4	NS	NS	NO MASS	NAD	UTERUS-BULKY	NAD	10	Easy	Easy	Adq	Scanty	Proliferative endometrium
75	13014	40	1 year	22.10.14	P_3L_3	HTN	NS	NO MASS	NAD	UTERUS-BULKY	INFLAMATORY	8	Easy	Easy	Adq	Adq	Proliferative endometrium
76	13016	40	1 year	28.10.14	P_3L_3	NS	NS	NO MASS	NAD	UTERUS-BULKY	INFLAMATORY	15	Easy	Easy	Adq	Adq	Proliferative endometrium
77	13017	41	2 month	29.10.14	P_2L_2	NS	NS	NO MASS	NAD	UTERUS-BULKY	NAD	13	Not easy	Easy	Adq	Adq	Proliferative endometrium
78	13090	41	3 month	1.11.14	P_4L_4	Anemia	NS	NO MASS	NAD	UTERUS-BULKY	INFLAMATORY	18	Not easy	Easy	Adq	Adq	Secretory endometrium
79	14001	42	8 month	02.11.14	Nullipara	NS	MOTHER-BA	NO MASS	NAD	UTERUS-NS	INFLAMATORY	14	Easy	Easy	Adq	Adq	Secretory endometrium
80	14005	42	11 month	06.11.14	P_3L_3	NS	NS	NO MASS	NAD	UTERUS-NS	INFLAMATORY	16	Easy	Easy	Adq	Adq	Proliferative endometrium
81	14009	42	2 month	10.11.14	P_3L_3	NS	NS	NO MASS	NAD	UTERUS-BULKY	NAD	4	Easy	Easy	Adq	Adq	Proliferative endometrium
82	14020	42	4 month	21.11.14	P_2L_2	DM	MOTHER-DM	NO MASS	NAD	UTERUS-NS	INFLAMATORY	12	Easy	Easy	Adq	Adq	Proliferative endometrium
83	14021	45	5 month	22.11.14	P_2L_2	NS	NS	NO MASS	NAD	UTERUS-NS	NAD	14	Easy	Easy	Adq	Adq	Simple hyperplasia without atypia
84	14024	45	6 month	23.11.14	P_6L_6	NS	NS	NO MASS	BLEEDING +	UTERUS-NS	INFLAMATORY	12	Easy	Easy	Adq	Adq	Proliferative endometrium
85	14025	43	2 month	25.11.14	P_2L_2	HTN	NS	NO MASS	NAD	UTERUS-BULKY	INFLAMATORY	8	Easy	Easy	Adq	Adq	Secretory endometrium
86	14064	43	1 month	28.11.14	P_3L_3	NS	NS	NO MASS	NAD	UTERUS-BULKY	INFLAMATORY	4	Easy	Easy	Adq	Scanty	Secretory endometrium
87	14078	43	3 month	01.12.14	P_3L_3	NS	NS	NO MASS	NAD	UTERUS-BULKY	NAD	6	Easy	Easy	Adq	Adq	Secretory endometrium
88	14081	43	5 month	11.12.14	P_2L_2	HTN	BROTHER-CA LUNG	NO MASS	ECTROPION+	UTERUS-BULKY	INFLAMATORY	6	Easy	Easy	Adq	Adq	scanty endometrium
89	14083	44	6 month	13.12.14	P_2L_2	HTN+DM	NS	NO MASS	NAD	UTERUS-BULKY	NAD	7	Easy	Easy	Adq	Adq	Secretory endometrium
90	14085	44	8 month	15.12.14	P_4L_4	NS	NS	NO MASS	NAD	UTERUS-BULKY	INFLAMATORY	19	Easy	Easy	Adq	Adq	Proliferative endometrium
91	14086	44	11 month	18.12.14	P_2L_2	NS	NS	NO MASS	NAD	UTERUS-BULKY	NAD	7	Easy	Easy	Adq	Adq	Proliferative endometrium
92	14091	44	1 year	21.12.14	P_3L_3	HTN	NS	NO MASS	NAD	UTERUS-BULKY	NAD	4	Easy	Easy	Adq	Adq	Secretory endometrium
93	15012	44	2 month	24.12.14	P_3L_3	NS	NS	NO MASS	NAD	UTERUS-BULKY	NAD	10	Easy	Easy	Adq	Adq	Secretory endometrium
94	15014	41	3 month	28.12.14	P_5L_5	DM	NS	NO MASS	NAD	UTERUS-NS	INFLAMATORY	15	Not easy	Easy	Adq	Adq	Proliferative endometrium
95	15016	45	1 year	01.01.15	P_3L_3	HTN	NS	NO MASS	NAD	UTERUS-BULKY	INFLAMATORY	13	Easy	Easy	Adq	Adq	Secretory endometrium
96	15018	45	1 month	11.01.15	P_4L_4	NS	NS	NO MASS	NAD	UTERUS-BULKY	NAD	10	Easy	Easy	Adq	Adq	Proliferative endometrium

S. No	I.P. No	Age	AUB Duration	LMP	Party Index	Past History	Family History	Per abdomen	Per Speculum	Per vaginium	PAP smear	TAS ET (mm)	Sampling Procedure		Tissue adequacy		HPE
													Pipelle	Hysteroscopy directed biopsy	Pipelle	Hysteroscopy directed biopsy	
97	15020	45	4 month	12.01.15	P_3L_3	Anemia	NS	NO MASS	NAD	UTERUS-BULKY	INFLAMATORY	15	Easy	Easy	Adq	Adq	Secretory endometrium
98	15211	45	2 month	13.01.15	P_4L_4	NS	NS	NO MASS	NAD	UTERUS-BULKY	INFLAMATORY	15	Easy	Easy	Adq	Adq	Proliferative endometrium
99	15217	45	1 month	14.01.15	P_3L_3	NS	NS	NO MASS	BLEEDING +	UTERUS-BULKY	INFLAMATORY	16	Easy	Easy	Adq	Scanty	Secretory endometrium
100	15218	43	11 month	15.01.15	P_3L_3	NS	NS	NO MASS	NAD	UTERUS-BULKY	NAD	6	Easy	Easy	Adq	Adq	Simple hyperplasia
101	15300	42	1 year	16.01.15	P_2L_2	HTN	NS	NO MASS	NAD	UTERUS-BULKY	INFLAMATORY	14	Easy	Easy	Adq	Adq	Proliferative endometrium
102	15333	45	1 year	17.01.15	P_4L_4	NS	NS	NO MASS	NAD	UTERUS-BULKY	NAD	10	Easy	Easy	Adq	Adq	Secretory endometrium
103	15345	45	1 year	18.01.15	Nullipara	NS	NS	NO MASS	NAD	UTERUS-BULKY	INFLAMATORY	8	Easy	Easy	Adq	Adq	Proliferative endometrium
104	15436	40	1 year	19.01.15	P_3L_3	DM	NS	NO MASS	ECTROPION+	UTERUS-BULKY	INFLAMATORY	15	Easy	Easy	Adq	Adq	Secretory endometrium
105	15646	41	2 month	21.01.15	P_3L_3	NS	FATER-HTN	NO MASS	NAD	UTERUS-NS	INFLAMATORY	13	Easy	Easy	Adq	Adq	simple hyperplasia
106	15676	41	3 month	22.01.15	P_2L_2	HTN	NS-SISTER HTN	NO MASS	NAD	UTERUS-NS	NAD	18	Easy	Easy	Adq	Adq	Irregular shedding
107	15787	43	8 month	27.01.15	P_2L_2	NS	FATHER-CO-COLON	NO MASS	NAD	UTERUS-BULKY	INFLAMATORY	14	Easy	Easy	Adq	Adq	Proliferative endometrium
108	16767	40	11 month	12.02.15	P_6L_6	NS	NS	NO MASS	NAD	UTERUS-NS	NAD	16	Not easy	Easy	Adq	Adq	Irregular shedding
109	16989	40	2 month	13.02.15	P_2L_2	Anemia	NS	NO MASS	NAD	UTERUS-NS	INFLAMATORY	4	Not easy	Easy	Adq	Adq	simple hyperplasia
110	17020	41	4 month	14.02.15	P_3L_3	NS	NS	NO MASS	NAD	UTERUS-NS	NAD	12	Easy	Easy	Adq	Adq	Secretory endometrium
111	17121	41	5 month	16.02.15	P_3L_3	NS	NS	NO MASS	NAD	UTERUS-BULKY	NAD	14	Easy	Easy	Adq	Adq	Secretory endometrium
112	17212	42	6 month	21.02.15	P_2L_2	NS	NS	NO MASS	NAD	UTERUS-BULKY	NAD	12	Easy	Easy	Adq	Adq	Secretory endometrium
113	17316	42	2 month	22.02.15	P_2L_2	DM	NS	NO MASS	NAD	UTERUS-BULKY	INFLAMATORY	8	Easy	Easy	Adq	Scanty	Proliferative endometrium
114	17435	42	1 month	13.03.15	P_4L_4	NS	MOTHER-HTN	NO MASS	NAD	UTERUS-BULKY	INFLAMATORY	4	Easy	Easy	Adq	Adq	Proliferative endometrium
115	17564	42	3 month	14.03.15	P_2L_2	NS	NS	NO MASS	NAD	UTERUS-BULKY	NAD	6	Easy	Easy	Adq	Adq	Proliferative endometrium
116	17676	45	5 month	22.03.15	P_3L_3	HTN	NS	NO MASS	BLEEDING +	UTERUS-BULKY	INFLAMATORY	6	Easy	Easy	Adq	Adq	Proliferative endometrium
117	17777	45	6 month	25.03.15	P_3L_3	NS	NS	NO MASS	NAD	UTERUS-BULKY	INFLAMATORY	7	Easy	Easy	Adq	Adq	Secretory endometrium

S. No	I.P. No	Age	AUB Duration	LMP	Party Index	Past History	Family History	Per abdomen	Per Speculum	Per vaginium	PAP smear	TAS ET (mm)	Sampling Procedure		Tissue adequacy		HPE
													Pipelle	Hysteroscopy directed biopsy	Pipelle	Hysteroscopy directed biopsy	
118	17879	43	8 month	01.04.15	P_5L_5	NS	NS	NO MASS	NAD	UTERUS-BULKY	INFLAMATORY	19	Easy	Easy	Adq	Adq	scanty endometrium
119	17989	43	11 month	11.04.15	P_3L_3	HTN	NS	NO MASS	NAD	UTERUS-BULKY	NAD	7	Not easy	Easy	Adq	Adq	scanty endometrium
120	18001	43	1 year	12.04.15	P_4L_4	HTN+DM	NS	NO MASS	ECTROPION+	UTERUS-NS	INFLAMATORY	4	Easy	Easy	Adq	Adq	Secretory endometrium
121	18090	43	2 month	15.04.15	P_3L_3	NS	NS	NO MASS	NAD	UTERUS-BULKY	NAD	10	Easy	Easy	Adq	Adq	Secretory endometrium
122	18121	44	3 month	21.04.15	P_4L_4	NS	NS	NO MASS	NAD	UTERUS-BULKY	INFLAMATORY	15	Easy	Easy	Adq	Adq	Secretory endometrium
123	18232	44	1 year	22.04.15	P_3L_3	HTN	NS	NO MASS	NAD	UTERUS-BULKY	INFLAMATORY	13	Easy	Easy	Adq	Scanty	Proliferative endometrium
124	19020	44	1 month	23.04.15	P_3L_3	NS	NS	NO MASS	NAD	UTERUS-BULKY	INFLAMATORY	10	Easy	Easy	Scanty	Adq	Proliferative endometrium
125	19435	44	4 month	02.05.15	P_2L_2	DM	NS	NO MASS	NAD	UTERUS-BULKY	NAD	15	Easy	Easy	Adq	Adq	Proliferative endometrium
126	19768	44	2 month	03.05.15	P_4L_4	HTN	NS	NO MASS	NAD	UTERUS-BULKY	INFLAMATORY	15	Easy	Easy	Adq	Adq	Secretory endometrium
127	19898	41	1 month	21.05.15	Nullipara	NS	NS	NO MASS	NAD	UTERUS-BULKY	NAD	16	Easy	Easy	Adq	Adq	Secretory endometrium
128	19901	45	11 month	22.05.15	P_3L_3	Anemia	NS	NO MASS	NAD	UTERUS-BULKY	INFLAMATORY	6	Easy	Easy	Adq	Adq	Proliferative endometrium
129	19902	45	1 year	23.05.15	P_3L_3	NS	NS	NO MASS		UTERUS-BULKY	NAD	14	Easy	Easy	Adq	Adq	Secretory endometrium
130	19879	45	1 year	24.05.15	P_2L_2	NS	MOTHER-BA	NO MASS		UTERUS-BULKY	NAD	10	Easy	Easy	Adq	Adq	Proliferative endometrium

INSTITUTIONAL ETHICS COMMITTEE
MADRAS MEDICAL COLLEGE, CHENNAI-3

EC Reg No.ECR/270/Inst./TN/2013
Telephone No. 044 25305301
Fax : 044 25363970

CERTIFICATE OF APPROVAL

To
Dr. G.S.Vaishnavi,
Postgraduate M.S.(Obstetrics and Gynaecology),
Madras Medical College,
Chennai – 600 003.

Dear Dr.G.S.Vaishnavi,

The Institutional Ethics Committee has considered your request and approved your study titled **"Efficacy of pipelle aspiration in diagnosing endometrial pathology in perimenopausal women with abnormal uterine bleeding – a comparative study". No.05102014.**

The following members of Ethics Committee were present in the meeting held on 07.10.2014 conducted at Madras Medical College, Chennai-3.

1. Dr.C.Rajendran, M.D.,	: Chairperson
2. Dr.R.Vimala, M.D., Dean, MMC, Ch-3	: Deputy Chairperson
3. Prof.B.Kalaiselvi, M.D., Vice-Principal, MMC, Ch-3	: Member Secretary
4. Prof.R.Nandhini, M.D., Inst.of Pharmacology, MMC	: Member
5. Prof.K.Ramadevi, Director i/c, Inst.of Biochemistry, MMC	: Member
6. Prof.Saraswathy, M.D., Director, Pathology, MMC, Ch-3	: Member
7. Prof.S.G.Sivachidambaram, M.D., Director i/c, Inst.of Internal Medicine, MMC	: Member
8. Thiru S.Rameshkumar, Administrative Officer	: Lay Person
9. Thiru S.Govindasamy, B.A., B.L.,	: Lawyer
10. Tmt.Arnold Saulina, M.A., MSW.,	: Social Scientist

We approve the proposal to be conducted in its presented form.

The Institutional Ethics Committee expects to be informed about the progress of the study and SAE occurring in the course of the study, any changes in the protocol and patients information/informed consent and asks to be provided a copy of the final report.

Member Secretary, Ethics Committee
MEMBER SECRETARY
INSTITUTIONAL ETHICS COMMITTEE
MADRAS MEDICAL COLLEGE
CHENNAI-600 003

INFORMATION SHEET

- Your specimen has been accepted.
- We are conducting a study on endometrial sampling among patients attending Government General Hospital, Chennai and for that your specimen may be valuable to us.
- The purpose of this study is to diagnose the pathology of endometrium easily with the help of certain special tests.
- We are selecting certain case and if your specimen is found eligible, we may be using your specimen to perform extra tests and special studies which in any way do not affect your final report or management.
- The privacy of the patients in the research will be maintained throughout the study. In the event of any publication or presentation resulting from the research. No personally identifiable information will be shared.
- Taking part in this study is voluntary. You are free to decide whether to participate in this study or to withdraw at any time; your decision will not result in any loss of benefits to which you are otherwise entitled.
- The results of the special study may be intimated to you at the end of the study period or during the study if anything is found abnormal which may aid in the management or treatment.

Signature of investigator

Signature of participant.

Date.

CONSENT FORM

Title :

Name : **Date :**

Age : **IP No :**

Sex : **Study Group No:**

I am informed about the details of the study.

I understood the details of the study. I accept to take part in the study.

I accept to undergo endometrial sampling at Government General Hospital. I accept to take part in the study without any compulsion.

I understood that taking part in this study will not harm me.

I have received the information sheet above the study.

I accept for anaesthetising me for the purpose of endometrial sampling.

I accept that during anaesthesia doctors or the hospital is not responsible for the side effects to the drugs.

Signature of the Patient.

ஆராய்ச்சி தகவல் தாள்

தங்களது கருப்பையின் உடபுற சுவரின் திசு இங்கு பெற்றுக் கொள்ளப்பட்டது.

சென்னை அரசு பொது மருத்துவமனைக்கு வரும் நோயாளிகளுக்கு ஏற்படும் கருப்பையின் அதிக உதிரப் போக்கு பற்றிய ஒரு ஆராய்ச்சி இங்கு நடைபெற்று வருகின்றது.

கருப்பையின் அதிக உதிரப்போக்கு ஏற்படுவதற்கு பற்பல காரணங்கள் உண்டு அதில் கர்பப்பை புற்றுநோயை சில சிறப்புப் பரிசோதனைகளின் மூலம் எளிதில் கண்டுபித்து ஆராய முடியும் என்பதே இந்த ஆராய்ச்சியின் நோக்கமாகும்.

நீங்களும் இந்த ஆராய்ச்சியில் பங்கேற்க நாங்கள் விரும்புகிறோம். இந்த ஆராய்ச்சியில் உங்களுடைய திசுக்கை எடுத்து சில சிறப்புப் பரிசோதனைக்கு உட்படுத்தி அதன் தகவல்களை ஆராய்வோம். ஆதனால் தங்களது நோயின் ஆய்வறிக்கையோ அல்லது சிகிச்சையோ பாதிப்புக்கு ஏற்படாது என்பதையும் தெரிவித்துக்கொள்கிறோம்.

முடிவுகளை அல்லது கருத்துக்களை வெளியிடும் போதோ அல்லது ஆராய்ச்சியின் போதோ தங்களது பெயரையோ அல்லது அடையாளங்களையோ வெளியிட மாட்டோம் என்பதையும் தெரிவித்துக்கொள்கிறோம்.

இந்த ஆராய்ச்சியில் பங்கேற்பது தங்களுடைய விருப்பத்தின் பேரில் தான் இருக்கிறது. மேலும் நீங்கள் எந்நேரமும் இந்த ஆராய்ச்சியிலிருந்து பின்வாங்கலாம் என்பதையும் தெரிவித்துக்கொள்கிறோம்.

இந்த சிறப்புப் பரிசோதனைகளின் முடிவுகளை ஆராய்ச்சியின் போது அல்லது ஆராய்ச்சியின் முடிவின் போது தங்களுக்கு அறிவிப்போம் என்பதையும் தெரிவித்துக்கொள்கிறோம்.

ஆராய்ச்சியாளர் கையொப்பம்

பங்கேற்பாளர் கையொப்பம்

தேதி:

ஆராய்ச்சி ஒப்புதல் கடிதம்

ஆராய்ச்சி தலைப்பு:

பெயர் : தேதி :

வயது : உள் நோயாளி எண் :

பால் : ஆராய்ச்சி சேர்க்கை எண்:

இந்த ஆராய்ச்சியின் விவரங்களும் அதன் நோக்கங்களும் முழுமையாக எனக்கு தெளிவாக விளக்கப்பட்டது.

எனக்கு விளக்கப்பட்ட விஷயங்களை நான் புரிந்து கொண்டு நான் எனது சம்மதத்தைத் தெரிவிக்கிறேன்.

எனக்கு கர்பப்பை உற்புற சுவரின் சதை பரிசோதனை செய்து கொள்ள சம்மதம்.

இந்த ஆராய்ச்சியில் பிறரின் நிர்ப்பந்தமின்றி என் சொந்த விருப்பத்தின் பேரில் தான் பங்கு பெறுகிறேன் மற்றும் நான் இந்த ஆராய்ச்சியிலிருந்து எந்நேரமும் பின்வாங்கலாம் என்பதையும் அதனால் எந்த பாதிப்பும் ஏற்படாது என்பதையம் நான் புரிந்து கொண்டேன்.

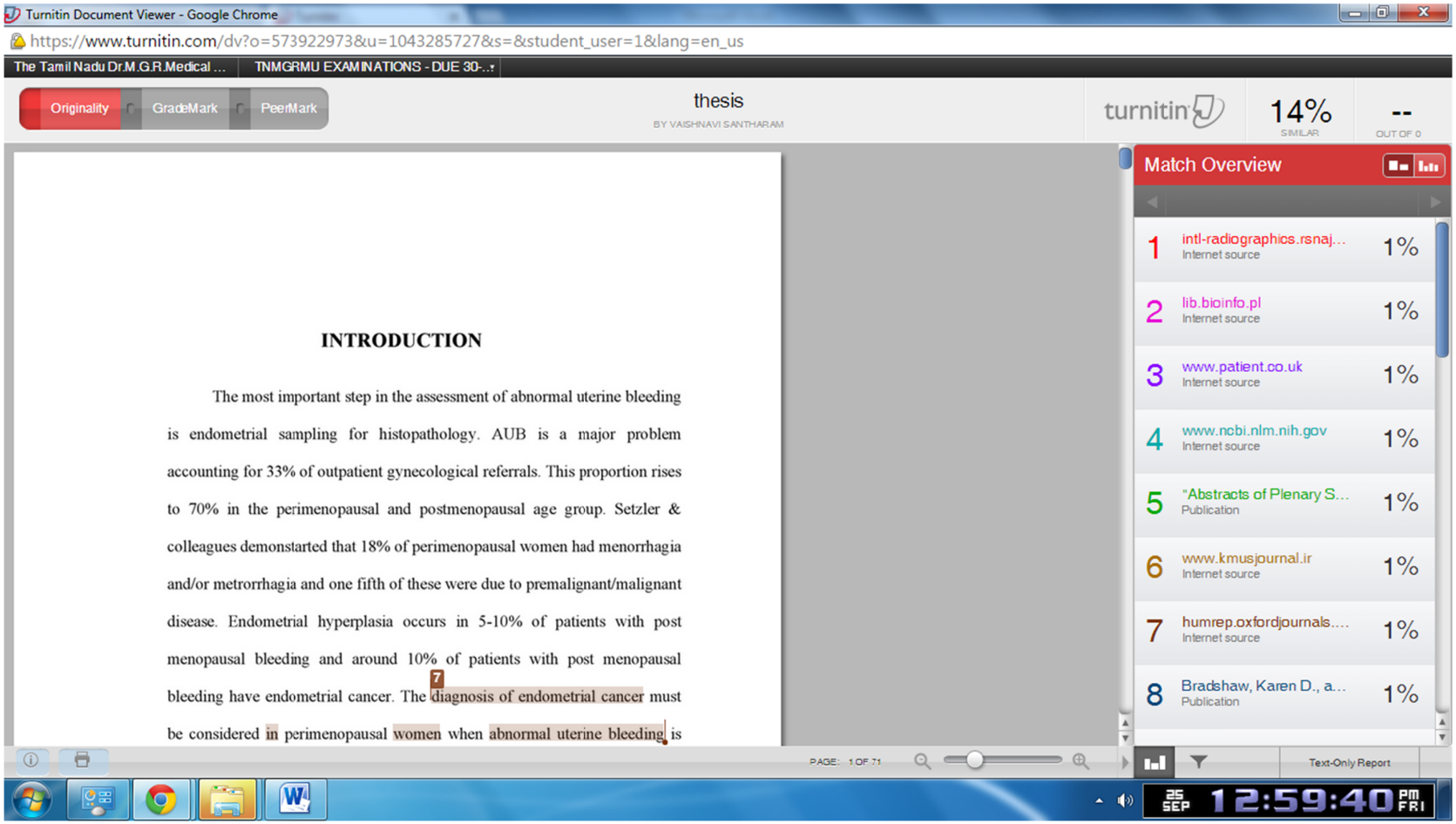
நான் கர்பப்பை திசு பரிசோதனை குறித்த இந்த ஆராய்ச்சியின் விவரங்களைக் கொண்ட தகவல் தாளைப் பெற்றுக் கொண்டேன்.

நான் என்னுடைய சுயநினைவுடன் மற்றும் முழு சுதந்திரத்துடன் இந்த மருத்துவ ஆராய்ச்சியில் என்னை சேர்த்துக் கொள்ள சம்மதிக்கிறேன்.

சதைப் பரிசோதனை செய்வதற்கு முன் வலி தெரியாமல் இருப்பதற்காக மயக்க மருந்து போடுவதற்கும் சம்மதிக்கிறேன்.

மேற்கண்ட் ஊசியை போடும் போதோ அல்லது சதை பரிசோதனை செய்யும் போதோ ஏதேனும் பின் விளைவுகள் (அரிப்பு, தோல் வீக்கம், தலைச்சுற்றல், வாந்தி முதலியன) ஏற்படலாம் என மருத்துவர் மூலம் தெரிந்து கொண்டேன்.

கையொப்பம்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The most important step in the assessment of abnormal uterine bleeding is endometrial sampling for histopathology. AUB is a major problem accounting for 33% of outpatient gynecological referrals. This proportion rises to 70% in the perimenopausal and postmenopausal age group. Setzler & colleagues demonstarted that 18% of perimenopausal women had menorrhagia and/or metrorrhagia and one fifth of these were due to premalignant/malignant disease. Endometrial hyperplasia occurs in 5-10% of patients with post menopausal bleeding and around 10% of patients with post menopausal bleeding have endometrial cancer. The diagnosis of endometrial cancer must be considered in perimenopausal women when abnormal uterine bleeding is
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INTRODUCTION

The most important step in the assessment of abnormal uterine bleeding is endometrial sampling for histopathology. AUB is a major problem accounting for 35% of outpatient gynaecological referrals. This proportion rises to 75% in the perimenopausal and postmenopausal age group. Fetcher & colleagues demonstrated that 14% of perimenopausal women had menorrhagia and/or metrorrhagia and one fifth of these were due to premalignant/malignant disease. Endometrial hyperplasia occurs in 5-10% of patients with post menopausal bleeding and around 10% of patients with post menopausal bleeding have endometrial cancer. The diagnosis of endometrial cancer must be considered in perimenopausal women when abnormal uterine bleeding is persistent or recurrent or if obesity or chronic anovulation is present. Endometrial sampling becomes mandatory when a woman is found to have high risk factors for endometrial pathology, such as postmenopausal bleeding, perimenopausal bleeding or history of chronic anovulation.

To date, hysteroscopic directed biopsy and D&C is considered as the standard for sampling the endometrium without in place in gynecology being challenged. Due to >60% of D&C, less than half of uterine cavity is curetted,